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 Legislation website at www.legislation.gov.au.

The information is not intended to give or replace any legal, medical, dental or optometrical advice. This document is not a legal document and does not constitute legal advice. Neither the information nor this document can be relied upon without first seeking and obtaining independent legal, medical, dental or optometrical advice beforehand. To the extent permitted by law, the Commonwealth of Australia will not be held responsible, nor accept any liability (whether arising out of negligence or otherwise), for any injury, damages, costs, expenses and losses suffered or incurred by a person where such a person has relied on this document or used the information in it as legal, medical, dental or optometrical advice.
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Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 December 2020 and are included, where applicable, in prices published in the Schedule —

<table>
<thead>
<tr>
<th>Dispensing Fees:</th>
<th>Ready-prepared</th>
<th>$7.74</th>
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<tbody>
<tr>
<td>Dangerous drug fee</td>
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<td>Extemporaneously-prepared</td>
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<tr>
<td>Allowable additional patient charge*</td>
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<tr>
<th>Additional Fees (for safety net prices):</th>
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<th>Patient Co-payments:</th>
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<table>
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<tr>
<th>Safety Net Thresholds:</th>
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<tr>
<td></td>
<td>Concessional</td>
<td>$316.80</td>
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</table>

Safety Net Card Issue Fee: $10.27

* 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 December 2020. 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

<table>
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<tr>
<th>Addition – Item</th>
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<tbody>
<tr>
<td><strong>12183F</strong></td>
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<tr>
<td><strong>12209N</strong></td>
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<td><strong>12203G</strong></td>
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<tr>
<td><strong>12198B</strong></td>
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<td><strong>12211Q</strong></td>
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<td><strong>12191P</strong></td>
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<td><strong>12190N</strong></td>
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<td><strong>12200D</strong></td>
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<td><strong>12189M</strong></td>
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<td><strong>12215X</strong></td>
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<td><strong>12192Q</strong></td>
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<td><strong>12197Y</strong></td>
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<td><strong>12188L</strong></td>
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<tr>
<td><strong>12199C</strong></td>
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<td><strong>12205J</strong></td>
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Addition – Brand

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<td><strong>10778G</strong></td>
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<td><strong>11934D</strong></td>
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<td><strong>3119E</strong></td>
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<td><strong>3318P</strong></td>
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<td><strong>9296G</strong></td>
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<td><strong>1810G</strong></td>
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<tr>
<td><strong>2414C</strong></td>
</tr>
<tr>
<td><strong>2412Y</strong></td>
</tr>
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</table>
11669E NOUMED LANSOPRAZOLE, VO – LANSOPRAZOLE, lansoprazole 30 mg enteric capsule, 28
2240X NOUMED LANSOPRAZOLE, VO – LANSOPRAZOLE, lansoprazole 30 mg enteric capsule, 28
2241Y NOUMED LANSOPRAZOLE, VO – LANSOPRAZOLE, lansoprazole 30 mg enteric capsule, 28
10526B Pharmacor Lurasidone, CR – LURASIDONE, lurasidone hydrochloride 40 mg tablet, 30
10529E Pharmacor Lurasidone, CR – LURASIDONE, lurasidone hydrochloride 80 mg tablet, 30
8561N APX-Meloxicam, TY – MELOXICAM, meloxicam 7.5 mg tablet, 30
8562P APX-Meloxicam, TY – MELOXICAM, meloxicam 15 mg tablet, 30
1598D MERCAPTOPURINE-LINK, LM – MERCAPTOPURINE, mercaptopurine monohydrate 50 mg tablet, 25
2430X APX-Metformin, TY – METFORMIN, metformin hydrochloride 500 mg tablet, 100
9435N Pharmacor Metformin XR, CR – METFORMIN, metformin hydrochloride 500 mg modified release tablet, 120
1801T APX-Metformin, TY – METFORMIN, metformin hydrochloride 850 mg tablet, 60
3439B Pharmacor Metformin XR, CR – METFORMIN, metformin hydrochloride 1 g modified release tablet, 60
8607B APX-Metformin, TY – METFORMIN, metformin hydrochloride 1 g tablet, 90
10460M Posaconazole Juno, JU – POSACONAZOLE, posaconazole 100 mg modified release tablet, 24
9202H APX-Quetiapine XR, TY – QUETIAPINE, quetiapine 50 mg modified release tablet, 60
5458G APX-Quetiapine XR, TY – QUETIAPINE, quetiapine 150 mg modified release tablet, 60
9203J APX-Quetiapine XR, TY – QUETIAPINE, quetiapine 200 mg modified release tablet, 60
9204K APX-Quetiapine XR, TY – QUETIAPINE, quetiapine 300 mg modified release tablet, 60
9205L APX-Quetiapine XR, TY – QUETIAPINE, quetiapine 400 mg modified release tablet, 60
11670F Rabeprazole Mylan, AF – RABEPRAZOLE, rabeprazole sodium 20 mg enteric tablet, 30
8508T Rabeprazole Mylan, AF – RABEPRAZOLE, rabeprazole sodium 20 mg enteric tablet, 30
8509W Rabeprazole Mylan, AF – RABEPRAZOLE, rabeprazole sodium 20 mg enteric tablet, 30
10785P Trimethoprim Mylan, AL – TRIMETHOPRIM, trimethoprim 300 mg tablet, 7
2666H Trimethoprim Mylan, AL – TRIMETHOPRIM, trimethoprim 300 mg tablet, 7
2922T Trimethoprim Mylan, AL – TRIMETHOPRIM, trimethoprim 300 mg tablet, 7
Addition – Equivalence Indicator
1598D Purinethol, AS – MERCAPTOPURINE, mercaptopurine monohydrate 50 mg tablet, 25
Addition – Note
2775C NORETHISTERONE + ETHINYLESTRADIOL, norethisterone 1 mg + ethinylestradiol 35 microgram tablet [21] (& inert substance tablet [7], 4 x 28 (Brevinor-1, Norimin-1 28 Day)
11624T VENETOCLAX, venetoclax 10 mg tablet, 14 (Venclexta)
11648C VENETOCLAX, venetoclax 50 mg tablet, 7 (Venclexta)
Addition – Restriction
2775C NORETHISTERONE + ETHINYLESTRADIOL, norethisterone 1 mg + ethinylestradiol 35 microgram tablet [21] (& inert substance tablet [7], 4 x 28 (Brevinor-1, Norimin-1 28 Day)
Deletions
Deletion – Item
1002R ACICLOVIR, aciclovir 3% eye ointment, 4.5 g (Zovirax)
5501M ACICLOVIR, aciclovir 3% eye ointment, 4.5 g (Zovirax)
1474N FLUCONAZOLE, fluconazole 200 mg/100 mL injection, 100 mL vial (Fluconazole Sandoz)
1041T OLANZAPINE, olanzapine 7.5 mg tablet, 28 (Olanzapine genenerichealth 7.5)
9360P POSACONAZOLE, posaconazole 40 mg/mL oral liquid, 105 mL (Noxafil)
Deletion – Brand
10460M  Noxafil, MK – POSACONAZOLE, posaconazole 100 mg modified release tablet, 24

Deletion – Note
1841X  POTASSIUM CHLORIDE, potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 200 (Span-K)
5442K  TOBRAMYCIN, tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules (TOBRAMYCIN SUN, TOBRAMYCIN WOCKHARDT, Tobi, Tobramycin WKT)

Deletion – Restriction
1841X  POTASSIUM CHLORIDE, potassium chloride 600 mg (potassium 8 mmol) modified release tablet, 200 (Span-K)

Alterations
Alteration – Item Description
From
12132M  AFLIBERCEPT, aflibercept 4 mg/0.1 mL injection, 0.09 mL syringe (Eylea)
To
12132M  AFLIBERCEPT, aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe (Eylea)
From
12141B  AFLIBERCEPT, aflibercept 4 mg/0.1 mL injection, 0.09 mL syringe (Eylea)
To
12141B  AFLIBERCEPT, aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe (Eylea)
From
12152N  AFLIBERCEPT, aflibercept 4 mg/0.1 mL injection, 0.09 mL syringe (Eylea)
To
12152N  AFLIBERCEPT, aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe (Eylea)
From
12153P  AFLIBERCEPT, aflibercept 4 mg/0.1 mL injection, 0.09 mL syringe (Eylea)
To
12153P  AFLIBERCEPT, aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe (Eylea)
From
11306C  TENOFOVIR + EMTRICITABINE, tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30 (Tenofovir EMT GH)
To
11306C  TENOFOVIR DISOPROXIL + EMTRICITABINE, tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30 (Tenofovir EMT GH)
From
11276L  TENOFOVIR + EMTRICITABINE, tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30 (Tenofovir/Emtricitabine 300/200 APOTEX)
To
11276L  TENOFOVIR DISOPROXIL + EMTRICITABINE, tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30 (Tenofovir/Emtricitabine 300/200 APOTEX)
From
11296M  TENOFOVIR + EMTRICITABINE, tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30 (Tenofovir Disoproxil Emtricitabine Mylan 300/200)
To
11296M  TENOFOVIR DISOPROXIL + EMTRICITABINE, tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30 (Tenofovir Disoproxil Emtricitabine Mylan 300/200)

Alteration – Note
9077R  ADALIMUMAB, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (Humira)
9078T  ADALIMUMAB, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (Humira)
9103D  ADALIMUMAB, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (Humira)
9104E  ADALIMUMAB, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (Humira)
10137M  CERTOLIZUMAB PEGOL, certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (Cimzia)
10897M  CERTOLIZUMAB PEGOL, certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (Cimzia)
10904X  CERTOLIZUMAB PEGOL, certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (Cimzia)
11318Q  CERTOLIZUMAB PEGOL, certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices (Cimzia)
11319R  CERTOLIZUMAB PEGOL, certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices (Cimzia)
11320T  CERTOLIZUMAB PEGOL, certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices (Cimzia)
11204Q  ETANERCEPT, etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (Enbrel)
8778B  **ETANERCEPT**, etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (Enbrel)

8779C  **ETANERCEPT**, etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (Enbrel)

11201M  **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL pen devices (Brenzys, Enbrel)

11215G  **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL pen devices (Brenzys)

9455P  **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL pen devices (Brenzys, Enbrel)

9456Q  **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes (Brenzys, Enbrel)

9085E  **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes (Brenzys, Enbrel)

9086F  **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes (Brenzys, Enbrel)

11361Y  **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL pen device (Simponi)

11361Y  **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL pen device (Simponi)

3434R  **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (Simponi)

3436W  **GOLIMUMAB**, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (Simponi)

10890E  **SECUKINUMAB**, secukinumab 150 mg/mL injection, 1 mL pen device (Cosentyx)

10893H  **SECUKINUMAB**, secukinumab 150 mg/mL injection, 1 mL pen device (Cosentyx)

10906B  **SECUKINUMAB**, secukinumab 150 mg/mL injection, 1 mL pen device (Cosentyx)

**Alteration – Restriction**

11624T  **VENETOCLAX**, venetoclax 10 mg tablet, 14 (Venclexta)

11648C  **VENETOCLAX**, venetoclax 50 mg tablet, 7 (Venclexta)

11639N  **VENETOCLAX**, venetoclax 100 mg tablet, 120 (Venclexta)

**Alteration – Manufacturer Code**

5140M  **Saphris** – **ASENAPINE**, asenapine 5 mg sublingual wafer, 60  From  To

5141N  **Saphris** – **ASENAPINE**, asenapine 10 mg sublingual wafer, 60  LU  OQ

2694T  **Celestone Chronodose** – **BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE**, betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL (total betamethasone 5.7 mg/mL) injection, 5 x 1 mL ampoules  MK  OQ

5034Y  **Celestone Chronodose** – **BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE**, betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL (total betamethasone 5.7 mg/mL) injection, 5 x 1 mL ampoules  MK  OQ

10800K  **Diprosone** – **BETAMETHASONE DIPROPIONATE**, betamethasone (as dipropionate) 0.05% cream, 15 g  MK  OQ

10800K  **Eleuphrat** – **BETAMETHASONE DIPROPIONATE**, betamethasone (as dipropionate) 0.05% cream, 15 g  FR  OV

10801L  **Diprosone** – **BETAMETHASONE DIPROPIONATE**, betamethasone (as dipropionate) 0.05% cream, 15 g  MK  OQ

10801L  **Eleuphrat** – **BETAMETHASONE DIPROPIONATE**, betamethasone (as dipropionate) 0.05% cream, 15 g  FR  OV

10802M  **Diprosone** – **BETAMETHASONE DIPROPIONATE**, betamethasone (as dipropionate) 0.05% cream, 15 g  MK  OQ

10802M  **Eleuphrat** – **BETAMETHASONE DIPROPIONATE**, betamethasone (as dipropionate) 0.05% cream, 15 g  FR  OV

10813D  **Diprosone** – **BETAMETHASONE DIPROPIONATE**, betamethasone (as dipropionate) 0.05% cream, 15 g  MK  OQ

10813D  **Eleuphrat** – **BETAMETHASONE DIPROPIONATE**, betamethasone (as dipropionate) 0.05% cream, 15 g  FR  OV
10824Q Diprosone – BETAMETHASONE DIPROPIONATE, betamethasone (as dipropionate) 0.05% cream, 15 g MK OQ
10824Q Eleuphrat – BETAMETHASONE DIPROPIONATE, betamethasone (as dipropionate) 0.05% cream, 15 g FR OV
1115Q Diprosone – BETAMETHASONE DIPROPIONATE, betamethasone (as dipropionate) 0.05% cream, 15 g MK OQ
1115Q Eleuphrat – BETAMETHASONE DIPROPIONATE, betamethasone (as dipropionate) 0.05% cream, 15 g FR OV
10795E Diprosone – BETAMETHASONE DIPROPIONATE, betamethasone (as dipropionate) 0.05% ointment, 15 g MK OQ
10795E Eleuphrat – BETAMETHASONE DIPROPIONATE, betamethasone (as dipropionate) 0.05% ointment, 15 g FR OV
10816G Diprosone – BETAMETHASONE DIPROPIONATE, betamethasone (as dipropionate) 0.05% ointment, 15 g MK OQ
10816G Eleuphrat – BETAMETHASONE DIPROPIONATE, betamethasone (as dipropionate) 0.05% ointment, 15 g FR OV
10820L Diprosone – BETAMETHASONE DIPROPIONATE, betamethasone (as dipropionate) 0.05% ointment, 15 g MK OQ
10820L Eleuphrat – BETAMETHASONE DIPROPIONATE, betamethasone (as dipropionate) 0.05% ointment, 15 g FR OV
10821M Diprosone – BETAMETHASONE DIPROPIONATE, betamethasone (as dipropionate) 0.05% ointment, 15 g MK OQ
10821M Eleuphrat – BETAMETHASONE DIPROPIONATE, betamethasone (as dipropionate) 0.05% ointment, 15 g FR OV
10823P Diprosone – BETAMETHASONE DIPROPIONATE, betamethasone (as dipropionate) 0.05% ointment, 15 g MK OQ
10823P Eleuphrat – BETAMETHASONE DIPROPIONATE, betamethasone (as dipropionate) 0.05% ointment, 15 g FR OV
1119X Diprosone – BETAMETHASONE DIPROPIONATE, betamethasone (as dipropionate) 0.05% ointment, 15 g MK OQ
1119X Eleuphrat – BETAMETHASONE DIPROPIONATE, betamethasone (as dipropionate) 0.05% ointment, 15 g FR OV
2812B Antroquoril – BETAMETHASONE VALERATE, betamethasone (as valerate) 0.02% cream, 100 g FR OV
2812B Celestone-M – BETAMETHASONE VALERATE, betamethasone (as valerate) 0.02% cream, 100 g MK OQ
8487Q Implanon NXT – ETONOGESTREL, etonogestrel 68 mg implant, 1 MK OQ
8565T Puregon 300 IU/0.36 mL – FOLLITROPIN BETA, follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge MK OQ
8566W Puregon 600 IU/0.72 mL – FOLLITROPIN BETA, follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge MK OQ
8871X Puregon 900 IU/1.08 mL – FOLLITROPIN BETA, follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge MK OQ
11148R Pregnyl – HUMAN CHORIONIC GONADOTROPIN, human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack MK OQ
11890T Sinemet CR Prolonged-Release Tablets – LEVODOPA + CARBIDOPA, levodopa 200 mg + carbidopa 50 mg modified release tablet, 60 MK OQ
10005N Sevikar HCT 20/5/12.5 – OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE, olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30 MK AF
2864R Sevikar HCT 40/5/25 – OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE, olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30 MK AF
<table>
<thead>
<tr>
<th>Code</th>
<th>Product Name</th>
<th>Code</th>
<th>Product Name</th>
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</thead>
<tbody>
<tr>
<td>2880N</td>
<td>Sevikar HCT 40/5/12.5 – OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE, olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30</td>
<td>2836G</td>
<td>Sevikar HCT 40/10/12.5 – OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE, olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30</td>
</tr>
</tbody>
</table>

**Supply Only**

From 1 November 2020 when a product is deleted from the Schedule it may now be available under new Supply Only rules. Supply Only items/brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it is deleted.

Substitution of Supply Only items/brands with products flagged as "equivalent for substitution" still apply as specified in the Schedule at the time the script was written. Further information on Supply Only arrangements is available at www.pbs.gov.au

**Supply Only commencing 1 December 2020**

<table>
<thead>
<tr>
<th>Code</th>
<th>Product Name</th>
<th>Code</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>2977Q</td>
<td>Austrapen, AL – AMPICILLIN, ampicillin 1 g injection, 5 vials</td>
<td>3314K</td>
<td>Austrapen, AL – AMPICILLIN, ampicillin 1 g injection, 5 vials</td>
</tr>
<tr>
<td>9296G</td>
<td>Clopidogrel/Aspirin Sandoz 75/100, SZ – CLOPIDOGREL + ASPIRIN, clopidogrel 75 mg + aspirin 100 mg tablet, 30</td>
<td>8700X</td>
<td>Esitalo, SZ – ESCITALOPRAM, escitalopram 10 mg tablet, 28</td>
</tr>
<tr>
<td>8701Y</td>
<td>Esitalo, SZ – ESCITALOPRAM, escitalopram 20 mg tablet, 28</td>
<td>1567L</td>
<td>Inza 50, AF – MINOCYCLINE, minocycline 50 mg tablet, 60</td>
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<tr>
<td>9435N</td>
<td>Diaformin XR, AF – METFORMIN, metformin hydrochloride 500 mg modified release tablet, 120</td>
<td>2234N</td>
<td>Pentasa, FP - MESALAZINE, mesalazine 1 g modified release granules, 120 sachets</td>
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<tr>
<td>8752P</td>
<td>Pentasa, FP - MESALAZINE, mesalazine 1 g suppository, 30</td>
<td>1629R</td>
<td>Hydopa, AF – METHYLDOPA, methyldopa 250 mg tablet, 100</td>
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<tr>
<td>1616C</td>
<td>Akamin 50, AF – MINOCYCLINE, minocycline 50 mg tablet, 60</td>
<td>1674D</td>
<td>Inza 250, AF – NAPROXEN, naproxen 250 mg tablet, 50</td>
</tr>
<tr>
<td>5176K</td>
<td>Inza 250, AF – NAPROXEN, naproxen 250 mg tablet, 50</td>
<td>1659H</td>
<td>Inza 500, AF – NAPROXEN, naproxen 500 mg tablet, 50</td>
</tr>
<tr>
<td>5177L</td>
<td>Inza 500, AF – NAPROXEN, naproxen 500 mg tablet, 50</td>
<td>2723H</td>
<td>Alodorm, AF – NITRAZEPAM, nitrazepam 5 mg tablet, 25</td>
</tr>
<tr>
<td>5189D</td>
<td>Alodorm, AF – NITRAZEPAM, nitrazepam 5 mg tablet, 25</td>
<td>3132W</td>
<td>Alepam 15, AF – OXAZEPAM, oxazepam 15 mg tablet, 25</td>
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<td>3134Y</td>
<td>Alepam 15, AF – OXAZEPAM, oxazepam 15 mg tablet, 25</td>
<td>5192G</td>
<td>Alepam 15, AF – OXAZEPAM, oxazepam 15 mg tablet, 25</td>
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<td>3133X</td>
<td>Alepam 30, AF – OXAZEPAM, oxazepam 30 mg tablet, 25</td>
<td>5135B</td>
<td>Alepam 30, AF – OXAZEPAM, oxazepam 30 mg tablet, 25</td>
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<td>5193H</td>
<td>Alepam 30, AF – OXAZEPAM, oxazepam 30 mg tablet, 25</td>
<td>8694N</td>
<td>Pioglitazone Sandoz, SZ – PIOGLITAZONE, pioglitazone 15 mg tablet, 28</td>
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<tr>
<td>1978D</td>
<td>Ranitidine Sandoz, SZ – RANITIDINE, ranitidine 150 mg tablet, 60</td>
<td>1977C</td>
<td>Ranitidine Sandoz, SZ – RANITIDINE, ranitidine 300 mg tablet, 30</td>
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<tr>
<td>8301X</td>
<td>Venlafaxine Sandoz XR, SZ – VENLAFAXINE, venlafaxine 75 mg modified release capsule, 28</td>
<td>8302Y</td>
<td>Venlafaxine Sandoz XR, SZ – VENLAFAXINE, venlafaxine 150 mg modified release capsule, 28</td>
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Advance Notices
1 January 2021
Deletion – Brand

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

1153Q NeoMercazole, BZ – CARBIMAZOLE, carbimazole 5 mg tablet, 100

5434B Clexane, SW – ENOXAPARIN SODIUM, enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes

5434B Enoxaparin Winthrop, WA – ENOXAPARIN SODIUM, enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes

5435C Clexane, SW – ENOXAPARIN SODIUM, enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes

5435C Enoxaparin Winthrop, WA – ENOXAPARIN SODIUM, enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes

8262W Clexane, SW – ENOXAPARIN SODIUM, enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes

8262W Enoxaparin Winthrop, WA – ENOXAPARIN SODIUM, enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes

8263X Clexane, SW – ENOXAPARIN SODIUM, enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes

8263X Enoxaparin Winthrop, WA – ENOXAPARIN SODIUM, enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes

8264Y Clexane, SW – ENOXAPARIN SODIUM, enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes

8264Y Enoxaparin Winthrop, WA – ENOXAPARIN SODIUM, enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes

8510X Clexane, SW – ENOXAPARIN SODIUM, enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes

8510X Enoxaparin Winthrop, WA – ENOXAPARIN SODIUM, enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes

8558K Clexane, SW – ENOXAPARIN SODIUM, enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes

8558K Enoxaparin Winthrop, WA – ENOXAPARIN SODIUM, enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes

8639Q Clexane, SW – ENOXAPARIN SODIUM, enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes

8639Q Enoxaparin Winthrop, WA – ENOXAPARIN SODIUM, enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes

8640R Clexane, SW – ENOXAPARIN SODIUM, enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes

8640R Enoxaparin Winthrop, WA – ENOXAPARIN SODIUM, enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes

8716R Clexane, SW – ENOXAPARIN SODIUM, enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes

8716R Enoxaparin Winthrop, WA – ENOXAPARIN SODIUM, enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes

8270G Prozac Tab, LY – FLUOXETINE, fluoxetine 20 mg tablet, 28

2269K DBL Vancomycin Hydrochloride, PF – VANCOMYCIN, vancomycin 1 g injection, 1 vial

2270L DBL Vancomycin Hydrochloride, PF – VANCOMYCIN, vancomycin 1 g injection, 1 vial

5083M DBL Vancomycin Hydrochloride, PF – VANCOMYCIN, vancomycin 1 g injection, 1 vial

1 February 2021
Deletion – Brand

10947E Jetrea, IJ – OCRIPLASMIN, ocriplasmin 500 microgram/0.2 mL injection, 0.2 mL vial

Palliative Care
Additions
Addition – Item

12210P PARACETAMOL, paracetamol 500 mg suppository, 10 (Panadol)
Supply Only
From 1 November 2020 when a product is deleted from the Schedule it may now be available under new Supply Only rules. Supply Only items/brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it is deleted. Substitution of Supply Only items/brands with products flagged as “equivalent for substitution” still apply as specified in the Schedule at the time the script was written. Further information on Supply Only arrangements is available at www.pbs.gov.au

Supply Only commencing 1 December 2020

5345H Inza 250, AF – NAPROXEN, naproxen 250 mg tablet, 50
5346J Inza 500, AF – NAPROXEN, naproxen 500 mg tablet, 50
5359C Alodorm, AF – NITRAZEPAM, nitrazepam 5 mg tablet, 25
5371Q Alepam 15, AF – OXAZEPAM, oxazepam 15 mg tablet, 25
5372R Alepam 30, AF – OXAZEPAM, oxazepam 30 mg tablet, 25

Highly Specialised Drugs Program (Private Hospital)
Additions

Addition – Item
12201E AMBRISENTAN, ambrisentan 5 mg tablet, 30 (Ambrisentan Mylan, Cipla Ambrisentan, Volibris)
12180C AMBRISENTAN, ambrisentan 10 mg tablet, 30 (Ambrisentan Mylan, Cipla Ambrisentan, Volibris)
12176W NUSINERSEN, nusinersen 12 mg/5 mL injection, 5 mL vial (Spinraza)

Addition – Brand
9648T Ambrisentan Mylan, AF – AMBRISENTAN, ambrisentan 5 mg tablet, 30
9648T Cipla Ambrisentan, LR – AMBRISENTAN, ambrisentan 5 mg tablet, 30
9649W Ambrisentan Mylan, AF – AMBRISENTAN, ambrisentan 10 mg tablet, 30
9649W Cipla Ambrisentan, LR – AMBRISENTAN, ambrisentan 10 mg tablet, 30
12150L TADALIS 20, LR – TADALAFIL, tadalafil 20 mg tablet, 56
1304P TADALIS 20, LR – TADALAFIL, tadalafil 20 mg tablet, 56

Addition – Equivalence Indicator
9648T Volibris, GK – AMBRISENTAN, ambrisentan 5 mg tablet, 30
9649W Volibris, GK – AMBRISENTAN, ambrisentan 10 mg tablet, 30

Alterations

Alteration – Item Description
From 12162D METHOXSALEN, methoxsalen 20 microgram/mL solution, 12 X 10 mL vial (Uvadex)
To 12162D METHOXSALEN, methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials (Uvadex)
From 12173Q METHOXSALEN, methoxsalen 20 microgram/mL solution, 12 X 10 mL vial (Uvadex)
To 12173Q METHOXSALEN, methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials (Uvadex)

Alteration – Note
11488P INFLIXIMAB, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Remflexis)
11489Q INFLIXIMAB, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Remflexis)
6448J INFLIXIMAB, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Remflexis)
11472T NUSINERSEN, nusinersen 12 mg/5 mL injection, 5 mL vial (Spinraza)

Alteration – Restriction
12139X BOSENTAN, bosentan 62.5 mg tablet, 60 (BOSENTAN DR. REDDY’S, BOSLEER, Bosentan APO, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer)
12148J BOSENTAN, bosentan 62.5 mg tablet, 60 (BOSENTAN DR. REDDY’S, BOSLEER, Bosentan APO, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer)
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<td>12146G</td>
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<tr>
<td>12135Q</td>
<td>MACITENTAN, macitentan 10 mg tablet, 30 (Opsumit)</td>
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<td>11472T</td>
<td>NUSINERSEN, nusinersen 12 mg/5 mL injection, 5 mL vial (Spinraza)</td>
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<td>11476B</td>
<td>NUSINERSEN, nusinersen 12 mg/5 mL injection, 5 mL vial (Spinraza)</td>
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<td>12138W</td>
<td>SILDENAFIL, sildenafil 20 mg tablet, 90 (APO-Sildenafil PHT, Revatio, SILDATIO PHT, Sildenafil AN PHT 20, Sildenafil Sandoz PHT 20)</td>
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<tr>
<td>12150L</td>
<td>TADALAFIL, tadalafil 20 mg tablet, 56 (Adcirca, TADALIS 20, Tadalca)</td>
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**Alteration – Manufacturer Code**

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<td>10184B</td>
<td>Renflexis – INFLIXIMAB, infliximab 100 mg injection, 1 vial</td>
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<td>11396T</td>
<td>Renflexis – INFLIXIMAB, infliximab 100 mg injection, 1 vial</td>
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<td>11399Y</td>
<td>Renflexis – INFLIXIMAB, infliximab 100 mg injection, 1 vial</td>
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<td>11445J</td>
<td>Renflexis – INFLIXIMAB, infliximab 100 mg injection, 1 vial</td>
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<td>9617E</td>
<td>Renflexis – INFLIXIMAB, infliximab 100 mg injection, 1 vial</td>
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<td>9674E</td>
<td>Renflexis – INFLIXIMAB, infliximab 100 mg injection, 1 vial</td>
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**Highly Specialised Drugs Program (Public Hospital)**

**Additions**

**Addition – Item**

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<td>AMBRISSENTAN, ambrisentan 5 mg tablet, 30 (Ambrisentan Mylan, Cipla Ambrisentan, Volibris)</td>
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<td>12186J</td>
<td>AMBRISSENTAN, ambrisentan 10 mg tablet, 30 (Ambrisentan Mylan, Cipla Ambrisentan, Volibris)</td>
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<td>12177X</td>
<td>NUSINERSEN, nusinersen 12 mg/5 mL injection, 5 mL vial (Spinraza)</td>
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**Addition – Brand**

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<td>Cipla Ambrisentan, LR – AMBRISENTAN, ambrisant 10 mg tablet, 30</td>
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**Alterations**

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<td>12154Q</td>
<td>METHOXSALEN, methoxsalen 20 microgram/mL solution, 12 X 10 mL vial (Uvadex)</td>
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**Alteration – Note**

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<td>NUSINERSEN, nusinersen 12 mg/5 mL injection, 5 mL vial (Spinraza)</td>
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**Alteration – Restriction**

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<tr>
<td>12134P</td>
<td>BOSENTAN, bosentan 62.5 mg tablet, 60 (BOSENTAN DR. REDDY'S, BOSLEER, Bosentan APO, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer)</td>
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<td>12145F</td>
<td>BOSENTAN, bosentan 62.5 mg tablet, 60 (BOSENTAN DR. REDDY'S, BOSLEER, Bosentan APO, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer)</td>
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<td>BOSENTAN, bosentan 125 mg tablet, 60 (BOSENTAN DR. REDDY'S, BOSLEER, Bosentan APO, Bosentan GH, Bosentan Mylan, Bosentan RBX, Bosentan Sandoz, Tracleer)</td>
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<td>12147H</td>
<td>MACITENTAN, macitentan 10 mg tablet, 30 (Opsumit)</td>
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<td>12144E</td>
<td>SILDENAFIL, sildenafil 20 mg tablet, 90 (APO-Sildenafil PHT, Revatio, SILDATIO PHT, Sildenafil AN PHT 20, Sildenafil Sandoz PHT 20)</td>
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<tr>
<td>12151M</td>
<td>TADALAFIL, tadalafil 20 mg tablet, 56 (Adcirca, TADALIS 20, Tadalca)</td>
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**Alteration – Manufacturer Code**

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## Highly Specialised Drugs Program (Community Access)

### Alterations

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<td>TENOFOVIR + EMTRICITABINE, tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30 (Tenofovir EMT GH)</td>
</tr>
<tr>
<td>To 11146P</td>
<td>TENOFOVIR DISOPROXIL + EMTRICITABINE, tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30 (Tenofovir EMT GH)</td>
</tr>
<tr>
<td>From 10347N</td>
<td>TENOFOVIR + EMTRICITABINE, tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30 (Tenofovir/Emtricitabine 300/200 APOTEX)</td>
</tr>
<tr>
<td>To 10347N</td>
<td>TENOFOVIR DISOPROXIL + EMTRICITABINE, tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30 (Tenofovir/Emtricitabine 300/200 APOTEX)</td>
</tr>
<tr>
<td>From 11149T</td>
<td>TENOFOVIR + EMTRICITABINE, tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30 (Tenofovir Disoproxil Emtricitabine Mylan 300/200)</td>
</tr>
<tr>
<td>To 11149T</td>
<td>TENOFOVIR DISOPROXIL + EMTRICITABINE, tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30 (Tenofovir Disoproxil Emtricitabine Mylan 300/200)</td>
</tr>
<tr>
<td>From 11732L</td>
<td>TENOFOVIR + EMTRICITABINE + EFAVIRENZ, tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30 (Tenofovir Disoproxil/Emtricitabine/Efavirenz Mylan 300/200/600)</td>
</tr>
<tr>
<td>To 11732L</td>
<td>TENOFOVIR DISOPROXIL + EMTRICITABINE + EFAVIRENZ, tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30 (Tenofovir Disoproxil/Emtricitabine/Efavirenz Mylan 300/200/600)</td>
</tr>
</tbody>
</table>

### Alteration – Restriction

<table>
<thead>
<tr>
<th>Alteration</th>
<th>Item Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11843H</td>
<td>DOLUTEGRAVIR + LAMIVUDINE, dolutegravir 50 mg + lamivudine 300 mg tablet, 30 (Dovato)</td>
</tr>
</tbody>
</table>

## Botulinum Toxin Program

### Additions

<table>
<thead>
<tr>
<th>Addition</th>
<th>Item Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>12214W</td>
<td>CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX, clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial (Dysport)</td>
</tr>
<tr>
<td>12178Y</td>
<td>CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX, clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial (Dysport)</td>
</tr>
</tbody>
</table>
Growth Hormone Program
Advance Notices
1 April 2021
Deletion – Brand

10437H Norditropin SimpleXx, NO – SOMATROPIN, somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge
10439K Norditropin SimpleXx, NO – SOMATROPIN, somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge
10448X Norditropin SimpleXx, NO – SOMATROPIN, somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge
10468Y Norditropin SimpleXx, NO – SOMATROPIN, somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge
6295H Norditropin SimpleXx, NO – SOMATROPIN, somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge
6296J Norditropin SimpleXx, NO – SOMATROPIN, somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge

IVF Program
Alterations
Alteration – Manufacturer Code

5816D Elova – CORIFOLLITROPIN ALFA, corifollitropin alfa 100 microgram/0.5 mL injection, 0.5 mL syringe
5817E Elova – CORIFOLLITROPIN ALFA, corifollitropin alfa 150 microgram/0.5 mL injection, 0.5 mL syringe
6335K Puregon 300 IU/0.36 mL – FOLLITROPIN BETA, follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge
6336L Puregon 600 IU/0.72 mL – FOLLITROPIN BETA, follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge
6464F Puregon 900 IU/1.08 mL – FOLLITROPIN BETA, follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge
9583J Orgalutran – GANIRELIX, ganirelix 250 microgram/0.5 mL injection, 0.5 mL syringe
9584K Orgalutran – GANIRELIX, ganirelix 250 microgram/0.5 mL injection, 5 x 0.5 mL syringes
11154C Pregnyl – HUMAN CHORIONIC GONADOTROPHIN, human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack
11156E Pregnyl – HUMAN CHORIONIC GONADOTROPHIN, human chorionic gonadotrophin 5000 units injection [1 vial] (&) inert substance diluent [1 mL vial], 1 pack

Repatriation Pharmaceutical Benefits
Additions
Addition – Item

12179B BICARBONATE + CITRIC ACID + TARTARIC ACID, sodium bicarbonate 1.76 g + citric acid 720 mg + sodium citrate 630 mg + tartaric acid 890 mg effervescent granules, 28 x 4 g sachets (Trust Cystitis Relief)
12184G DRESSING FOAM WITH SILICONE HEAVY EXUDATE, dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 10 (Mepilex Border Flex 595211)
12206K DRESSING FOAM WITH SILICONE HEAVY EXUDATE, dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10 (Mepilex Border Flex 595311)
12185H DRESSING FOAM WITH SILICONE HEAVY EXUDATE, dressing foam with silicone heavy exudate 15 cm x 20 cm dressing, 10 (Mepilex Border Flex 595611)
12216Y DRESSING FOAM WITH SILICONE HEAVY EXUDATE, dressing foam with silicone heavy exudate 16 cm x 20 cm dressing, 5 (Mepilex Border Sacrum 282050)
12195W DRESSING FOAM WITH SILICONE HEAVY EXUDATE, dressing foam with silicone heavy exudate 22 cm x 23 cm dressing, 6 (Mepilex Border Heel 282750)
12207L DRESSING FOAM WITH SILICONE HEAVY EXUDATE, dressing foam with silicone heavy exudate 22 cm x 25 cm dressing, 5 (Mepilex Border Sacrum 282450)
12213T DRESSING GELLING FIBRE, dressing gelling fibre 1 cm x 45 cm dressing, 5 (Exufiber 709908)
12182E DRESSING GELLING FIBRE, dressing gelling fibre 2 cm x 45 cm dressing, 5 (Exufiber 709909)
12187K DRESSING GELLING FIBRE, dressing gelling fibre 5 cm x 5 cm dressing, 10 (Exufiber 709900)
12181D DRESSING GELLING FIBRE, dressing gelling fibre 10 cm x 10 cm dressing, 10 (Exufiber 709901)
12202F DRESSING GELLING FIBRE, dressing gelling fibre 15 cm x 15 cm dressing, 10 (Exufiber 709903)
12208M DRESSING NON-ADHERENT WITH SILICONE, dressing non-adherent with silicone 5 cm x 7.5 cm dressing, 10 (Mepitel One 289100)
12196X DRESSING NON-ADHERENT WITH SILICONE, dressing non-adherent with silicone 10 cm x 18 cm dressing, 10 (Mepitel One 289500)
12194T MEBENDAZOLE, mebendazole 100 mg chewable tablet, 6 (Trust Deworm)

Addition – Brand
4077N Trust Aspirin EC 100, CR – ASPIRIN, aspirin 100 mg enteric tablet, 84
4082W CAL-600, PP – CALCIUM, calcium carbonate 1.5 g (calcium 600 mg) tablet, 120
4142B CAL-600, PP – CALCIUM, calcium carbonate 1.5 g (calcium 600 mg) tablet, 120
4175R Trust Cetirizine, CR – CETIRIZINE, cetirizine hydrochloride 10 mg tablet, 30
10169F BTC Clopidogrel, JB – CLOPIDOGREL, clopidogrel 75 mg tablet, 28
10169F Clopidogrel APOTEX, GX – CLOPIDOGREL, clopidogrel 75 mg tablet, 28
4238C Trust Fexit 120, CR – FEXOFENADINE, fexofenadine hydrochloride 120 mg tablet, 30
11710H Trust HydroCortic Cream, CR – HYDROCORTISONE ACETATE, hydrocortisone acetate 1% cream, 30 g
4313B Trust Loratadine, CR – LORATADINE, loratadine 10 mg tablet, 30
3431B Trust Loratadine Antihistamine, RM – LORATADINE, loratadine 10 mg tablet, 30
10854G Trust Nystatin Oral Drops, CR – NYSTATIN, nystatin 100 000 units/mL oral liquid, 24 mL
11711J Trust Decongestant Nasal Spray, CR – OXYMETAZOLINE, oxymetazoline hydrochloride 0.05% nasal spray, 20 mL
10599W Trust for Kids Paracetamol 6 to 12 years, CR – PARACETAMOL, paracetamol 240 mg/5 mL oral liquid, 200 mL
4029C Trust Sinus & Nasal Decongestant, CR – PSEUDOEPHEDRINE, pseudoephedrine hydrochloride 60 mg tablet, 12
4585H NOUMED Sildenafil, VO – SILDENAFIL, sildenafil 50 mg tablet, 4
4586J NOUMED Sildenafil, VO – SILDENAFIL, sildenafil 100 mg tablet, 4
4596X Cipla Tadalafil, LR – TADALAFIL, tadalafil 10 mg tablet, 4
4596X Tadalafil Sandoz, SZ – TADALAFIL, tadalafil 10 mg tablet, 4
4597Y Cipla Tadalafil, LR – TADALAFIL, tadalafil 20 mg tablet, 4
4597Y Tadalaccord, CR – TADALAFIL, tadalafil 20 mg tablet, 4
4597Y Tadalafil Sandoz, SZ – TADALAFIL, tadalafil 20 mg tablet, 4
4473K Trust Terbinafine Cream, CR – TERBINAFINE, terbinafine hydrochloride 1% cream, 15 g

Addition – Equivalence Indicator
4049D Uracol, EA – BICARBONATE + CITRIC ACID + TARTARIC ACID, sodium bicarbonate 1.76 g + sodium citrate 630 mg + citric acid 720 mg + tartaric acid 890 mg powder for oral liquid, 28 x 4 g sachets
4049D Ural Sachets, AS – BICARBONATE + CITRIC ACID + TARTARIC ACID, sodium bicarbonate 1.76 g + sodium citrate 630 mg + citric acid 720 mg + tartaric acid 890 mg powder for oral liquid, 28 x 4 g sachets
4082W CAL-600, PP – CALCIUM, calcium carbonate 1.5 g (calcium 600 mg) tablet, 120
4142B CAL-600, PP – CALCIUM, calcium carbonate 1.5 g (calcium 600 mg) tablet, 120
11710H Pharmacy Action Hydrocortisone Cream 1%, GQ – HYDROCORTISONE ACETATE, hydrocortisone acetate 1% cream, 30 g
| 4325P | Pharmacy Action Worm Treatment, GQ – MEBENDAZOLE, mebendazole 100 mg tablet, 6 |
| 1171J | Pharmacy Action Nasal Decongestant, GQ – OXYMETAZOLINE, oxymetazoline hydrochloride 0.05% nasal spray, 20 mL |
| 10599W | Panamax 240 Elixir, SW – PARACETAMOL, paracetamol 240 mg/5 mL oral liquid, 200 mL |
| 4596X | Cialis, LY – TADALAFIL, tadalafil 10 mg tablet, 4 |
| 4597Y | Cialis, LY – TADALAFIL, tadalafil 20 mg tablet, 4 |

**Addition – Note**

| 4049D | BICARBONATE + CITRIC ACID + TARTARIC ACID, sodium bicarbonate 1.76 g + sodium citrate 630 mg + citric acid 720 mg + tartaric acid 890 mg powder for oral liquid, 28 x 4 g sachets (Uracol, Ural Sachets) |
| 4325P | MEBENDAZOLE, mebendazole 100 mg tablet, 6 (Pharmacy Action Worm Treatment) |

**Deletions**

**Deletion – Item**

| 4071G | PHOLCODINE, pholcodine 1 mg/mL oral liquid, 100 mL (Gold Cross) |

**Alterations**

**Alteration – Item Description**

| From | To |
| 2462N | DRESSING HYDROFIBRE GELLING FIBRE, dressing hydrofibre gelling fibre 2 cm x 45 cm rope, 5 (Durafiber 66800563) |
| 2462N | DRESSING GELLING FIBRE, dressing gelling fibre 2 cm x 45 cm rope, 5 (Durafiber 66800563) |
| 2486W | DRESSING HYDROFIBRE GELLING FIBRE, dressing hydrofibre gelling fibre 10 cm x 10 cm dressing, 10 (Durafiber 66800560) |
| 2486W | DRESSING GELLING FIBRE, dressing gelling fibre 10 cm x 10 cm dressing, 10 (Durafiber 66800560) |
| 2445Q | DRESSING HYDROFIBRE GELLING FIBRE, dressing hydrofibre gelling fibre 15 cm x 15 cm dressing, 5 (Durafiber 66800561) |
| 2445Q | DRESSING GELLING FIBRE, dressing gelling fibre 15 cm x 15 cm dressing, 5 (Durafiber 66800561) |

**Alteration – Manufacturer Code**

| From | To |
| 4233T | Proscar – FINASTERIDE, finasteride 5 mg tablet, 30 |

**Supply Only**

From 1 November 2020 when a product is deleted from the Schedule it may now be available under new Supply Only rules. Supply Only items/brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it is deleted.

Substitution of Supply Only items/brands with products flagged as “equivalent for substitution” still apply as specified in the Schedule at the time the script was written. Further information on Supply Only arrangements is available at www.pbs.gov.au

**Supply Only commencing 1 December 2020**

| 4074K | Gold Cross, IL – AMMONIUM + SENEGA ROOT, ammonium bicarbonate 25 mg/mL + senega root 25 mg/mL oral liquid, 200 mL |
| 4115N | Zitrocin, GN – AZITHROMYCIN, azithromycin 500 mg tablet, 3 |
| 4026X | Gold Cross, IL – METHYL SALICYLATE, methyl salicylate 25% liniment, 100 mL |
| 4023R | Gold Cross, IL – METHYL SALICYLATE, methyl salicylate 50% ointment, 100 g |
| 4022Q | Gold Cross, IL – METHYL SALICYLATE + EUCALYPTUS OIL + MENTHOL, methyl salicylate 25% + eucalyptus oil 10% + menthol 4% cream, 100 g |

**Advance Notices**

**1 January 2021**

**Deletion – Brand**

| 4670T | Flexidress 650941, CC – BANDAGE ZINC PASTE, bandage zinc paste 10 cm x 9.1 m bandage, 1 |
4692Y  CombiDERM 651031, CC – 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

4693B  CombiDERM 651027, CC – DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM, dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 18 cm (foam alternative) dressing, 5

2464Q  Picato, LO – INGENOL MEBUTATE, ingenol mebutate 0.015% gel, 3 x 470 mg

2468X  Picato, LO – INGENOL MEBUTATE, ingenol mebutate 0.05% gel, 2 x 470 mg
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 and Abbreviations 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

DPMQ $ Dispensed price for maximum quantity

MRVSN $ Maximum recordable value for safety net

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

MP 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.
General Statement for Drugs for the Treatment of Hepatitis C

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

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

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

The following information must be provided at the time of application:
(a) the patient’s cirrhotic status (non-cirrhotic or cirrhotic)
(b) details of the previous treatment regimen (only for requests for sofosbuvir + velpatasvir + voxilaprevir (Vosevi®) or glecaprevir + pibrentasvir (Maviret®) for 16 weeks’ treatment in patients who have previously failed a treatment with a regimen containing an NS5A inhibitor).

The following information must be documented in the patient’s medical records:
(c) evidence of chronic hepatitis C infection (repeatedly antibody to hepatitis C virus (anti-HCV) positive and hepatitis C virus ribonucleic acid (HCV RNA) positive); and
(d) where possible, evidence of the hepatitis C virus genotype

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

### HEPATITIS C - NON-CIRRHOTIC PATIENTS

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Treatment Naive</th>
<th>Genotype</th>
<th>Treatment Experienced</th>
</tr>
</thead>
<tbody>
<tr>
<td>All genotypes (Pan-genotypic regimens)</td>
<td><strong>SOFOSBUVIR + VELPATASVIR [12 weeks]</strong> OR <strong>GLECAPREVIR + PIBRENTASVIR [8 weeks]</strong></td>
<td><strong>SOFOSBUVIR + VELPATASVIR [12 weeks]</strong> OR <strong>SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks]</strong> OR <strong>GLECAPREVIR + PIBRENTASVIR [8 or 12 or 16 weeks]</strong></td>
<td></td>
</tr>
<tr>
<td>Genotype 1</td>
<td><strong>LEDIPASVIR + SOFOSBUVIR [8 or 12 weeks]</strong> OR <strong>GRAZOPREVIR + ELBASVIR [12 weeks]</strong></td>
<td><strong>LEDIPASVIR + SOFOSBUVIR [12 weeks]</strong> OR <strong>GRAZOPREVIR + ELBASVIR [12 weeks]</strong> OR <strong>GRAZOPREVIR + ELBASVIR and RBV [16 weeks]</strong></td>
<td></td>
</tr>
<tr>
<td>Genotype 2</td>
<td>Refer to treatment naïve pan-genotypic regimens above.</td>
<td>Refer to treatment experienced pan-genotypic regimens above.</td>
<td></td>
</tr>
<tr>
<td>Genotype 3</td>
<td>Refer to treatment naïve pan-genotypic regimens above.</td>
<td>Refer to treatment experienced pan-genotypic regimens above.</td>
<td></td>
</tr>
<tr>
<td>Genotype 4</td>
<td><strong>GRAZOPREVIR + ELBASVIR [12 weeks]</strong></td>
<td><strong>GRAZOPREVIR + ELBASVIR [12 weeks]</strong> OR <strong>GRAZOPREVIR + ELBASVIR and RBV [16 weeks]</strong></td>
<td></td>
</tr>
<tr>
<td>Genotype 5 &amp; 6</td>
<td>Refer to treatment naïve pan-genotypic regimens above.</td>
<td>Refer to treatment experienced pan-genotypic regimens above.</td>
<td></td>
</tr>
</tbody>
</table>

**KEY**
RBV - ribavirin
### Hepatitis C – Cirrhotic Patients

<table>
<thead>
<tr>
<th>All genotypes (Pan-genotypic regimens)</th>
<th>Treatment Naïve</th>
<th>Treatment Experienced</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOFOSBUVIR + VELPATASVIR [12 weeks]</td>
<td>SOFOSBUVIR + VELPATASVIR [12 weeks]</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>GLECAPREVIR + PIBRENTASVIR [12 weeks]</td>
<td>GLECAPREVIR + PIBRENTASVIR + VOXILAPREVIR [12 weeks]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotype 1</th>
<th>LEDIPASVIR + SOFOSBUVIR [12 weeks]</th>
<th>LEDIPASVIR + SOFOSBUVIR [24 weeks]</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
<td>GRAZOPREVIR + ELBASVIR [12 weeks]</td>
<td>GRAZOPREVIR + ELBASVIR [12 weeks]</td>
</tr>
<tr>
<td></td>
<td>OR</td>
<td>OR + RBV [16 weeks]</td>
</tr>
<tr>
<td></td>
<td>GLECAPREVIR + PIBRENTASVIR [12 or 16 weeks]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotype 2</th>
<th>Refer to treatment naïve pan-genotypic regimens above.</th>
<th>Refer to treatment experienced pan-genotypic regimens above.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 3</td>
<td>Refer to treatment naïve pan-genotypic regimens above.</td>
<td>Refer to treatment experienced pan-genotypic regimens above.</td>
</tr>
<tr>
<td>Genotype 4</td>
<td>GRAZOPREVIR + ELBASVIR [12 weeks]</td>
<td>GRAZOPREVIR + ELBASVIR [12 weeks]</td>
</tr>
<tr>
<td></td>
<td>OR</td>
<td>OR + RBV [16 weeks]</td>
</tr>
</tbody>
</table>

**Key**

- **RBV** – ribavirin

1. **LEDIPASVIR + SOFOSBUVIR** [8 or 12 weeks] for treatment-naïve, non-cirrhotic patients:
   - consider treatment for 8 weeks where pre-treatment HCV RNA is less than 6 million IU/mL;
   - otherwise treatment for 12 weeks where pre-treatment HCV RNA is 6 million IU/mL or greater.
2. **GRAZOPREVIR + ELBASVIR and RBV** [16 weeks] for treatment-experienced, non-cirrhotic and cirrhotic patients, treatment for 16 weeks in patients with genotype 1a or 4 HCV who have experienced on-treatment virologic failure to prior treatment.
3. **GLECAPREVIR + PIBRENTASVIR** [8 or 12 or 16 weeks] for non-cirrhotic patients:
   - treatment for 8 weeks for treatment-experienced patients with genotypes 1, 2, 4, 5 or 6 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
   - treatment for 16 weeks for treatment-experienced patients with genotype 3 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
   - treatment for 12 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS3/4A PI;
   - treatment for 16 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS5A inhibitor.
4. **SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR** [12 weeks] only for patients who have failed an NS5A inhibitor.
5. **SOFOSBUVIR + VELPATASVIR** [12 weeks] for patients with decompensated cirrhosis. Use in combination with ribavirin.
6. **GLECAPREVIR + PIBRENTASVIR** [12 or 16 weeks] for cirrhotic patients:
   - treatment for 12 weeks for treatment-experienced patients with genotypes 1, 2, 4, 5 or 6 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
   - treatment for 16 weeks for treatment-experienced patients with genotype 3 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
   - treatment for 12 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS3/4A PI;
   - treatment for 16 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS5A inhibitor.
Pharmaceutical Benefits Schedules
Prescriber Bag
### ADRENALINE (EPINEPHRINE)

**adrenaline (epinephrine) 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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>21.68</td>
<td>Link Medical Products Pty Ltd [LM]</td>
</tr>
</tbody>
</table>

### ATROPINE SULFATE

**atropine sulfate monohydrate 600 microgram/mL injection, 10 x 1 mL ampoules**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>23.69</td>
<td>Pfizer Australia Pty Ltd [PF]</td>
</tr>
</tbody>
</table>

### BENZATHINE BENZYLPCINILLIN

**benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>304.76</td>
<td>Bicillin L-A [PF]</td>
</tr>
</tbody>
</table>

### BENZATROPINE

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>117.17</td>
<td>Benztropine Injection [FF]</td>
</tr>
</tbody>
</table>

### BENZYLPCINILLIN

**benzylpenicillin 600 mg injection, 1 vial**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>*41.74</td>
<td>BenPen [CS]</td>
</tr>
</tbody>
</table>

**OR**

### PROCAINE BENZYLPCINILLIN (PROCAINE PENICILLIN)

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>75.37</td>
<td>Cilicaine [AF]</td>
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</table>

### BENZYLPCINILLIN

**benzylpenicillin 3 g injection, 1 vial**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>21.60</td>
<td>BenPen [CS]</td>
</tr>
</tbody>
</table>

### CHLORPROMAZINE

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>21.94</td>
<td>Largactil [SW]</td>
</tr>
</tbody>
</table>

**OR**

### HALOPERIDOL

**haloperidol 5 mg/mL injection, 10 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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<tbody>
<tr>
<td>1</td>
<td>23.22</td>
<td>Serenate [AS]</td>
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### CLONAZEPAM

**clonazepam 2.5 mg/mL (0.1 mg/drop) oral liquid, 10 mL**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1</td>
<td>15.77</td>
<td>Rivotril [RO]</td>
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### DIPHTHERIA + TETANUS VACCINE

**diphtheria 2 units + tetanus 20 units vaccine 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>*129.74</td>
<td>ADT Booster [CS]</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Quantity and Formulation</td>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>-----------</td>
<td>--------------------------</td>
<td>---------------</td>
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<tr>
<td><strong>FUROSEMIDE (FRUSEMIDE)</strong>&lt;br&gt;furosemide (frusemide) 20 mg/2 mL injection, 5 x 2 mL ampoules</td>
<td>3466K</td>
<td>1</td>
</tr>
<tr>
<td><strong>GLUCAGON HYDROCHLORIDE</strong>&lt;br&gt;glucagon hydrochloride 1 mg injection [1 vial] (&amp;) inert substance diluent [1 mL syringe], 1 pack</td>
<td>3467L</td>
<td>1</td>
</tr>
<tr>
<td><strong>GLYCERYL TRINITRATE</strong>&lt;br&gt;glyceryl trinitrate 400 microgram/actuation spray, 200 actuations</td>
<td>3475X</td>
<td>1</td>
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<tr>
<td><strong>HYDROCORTISONE SODIUM SUCCINATE</strong>&lt;br&gt;hydrocortisone (as sodium succinate) 100 mg injection [1 chamber] (&amp;) inert substance diluent [2 mL chamber], 1 dual chamber vial</td>
<td>3470P</td>
<td>2</td>
</tr>
<tr>
<td>OR&lt;br&gt;hydrocortisone (as sodium succinate) 250 mg injection [1 chamber] (&amp;) inert substance diluent [2 mL chamber], 1 dual chamber vial</td>
<td>3471Q</td>
<td>1</td>
</tr>
<tr>
<td><strong>HYOSCINE BUTYLBROMIDE</strong>&lt;br&gt;hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules</td>
<td>3473T</td>
<td>1</td>
</tr>
<tr>
<td>* HYOSCINE BUTYLBROMIDE SXP [XC]</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>LIDOCAINE (LIGNOCAINE)</strong>&lt;br&gt;lidocaine (lignocaine) hydrochloride monohydrate 1% (50 mg/5 mL) injection, 5 x 5 mL ampoules</td>
<td>10209H</td>
<td>1</td>
</tr>
<tr>
<td><strong>METHOXYFLURANE</strong>&lt;br&gt;methoxyflurane 99.9% (999 mg/g) inhalation solution, 3 mL bottle</td>
<td>3489P</td>
<td>1</td>
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<tr>
<td><strong>METOCLOPRAMIDE</strong>&lt;br&gt;metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules</td>
<td>3476Y</td>
<td>1</td>
</tr>
<tr>
<td>OR&lt;br&gt;prochlorperazine mesilate 12.5 mg/mL injection, 10 x 1 mL ampoules</td>
<td>3477B</td>
<td>1</td>
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<tr>
<td><strong>MIDAZOLAM</strong>&lt;br&gt;midazolam 5 mg/mL injection, 10 x 1 mL ampoules</td>
<td>10178Q</td>
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**MORPHINE**

<table>
<thead>
<tr>
<th>Prescriber Bag</th>
<th>10862Q</th>
<th>morphine hydrochloride trihydrate 10 mg/mL injection, 5 x 1 mL ampoules</th>
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**OR**

<table>
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<tr>
<th>Prescriber Bag</th>
<th>10868B</th>
<th>morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules</th>
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<td>1</td>
<td><strong>DPMQ $</strong></td>
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<tr>
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<td>26.50</td>
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**OR**

<table>
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<tr>
<th>Prescriber Bag</th>
<th>3479D</th>
<th>morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules</th>
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<td><strong>Max Qty Packs</strong></td>
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<td><strong>DPMQ $</strong></td>
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<td></td>
<td></td>
<td>24.54</td>
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**OR**

<table>
<thead>
<tr>
<th>Prescriber Bag</th>
<th>3480E</th>
<th>morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules</th>
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</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
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<td><strong>DPMQ $</strong></td>
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<td></td>
<td></td>
<td>26.64</td>
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**NALOXONE**

<table>
<thead>
<tr>
<th>Prescriber Bag</th>
<th>10786Q</th>
<th>naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules</th>
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<tr>
<td><strong>Max Qty Packs</strong></td>
<td>2</td>
<td><strong>DPMQ $</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>*79.74</td>
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**OR**

<table>
<thead>
<tr>
<th>Prescriber Bag</th>
<th>11233F</th>
<th>naloxone hydrochloride 400 microgram/mL injection, 10 x 1 mL ampoules</th>
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</thead>
<tbody>
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<td><strong>DPMQ $</strong></td>
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<tr>
<td></td>
<td></td>
<td>79.74</td>
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**PHYTOMENADIONE**

<table>
<thead>
<tr>
<th>Prescriber Bag</th>
<th>10213M</th>
<th>phytomenadione 10 mg/mL injection, 5 x 1 mL ampoules</th>
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<tbody>
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<td><strong>DPMQ $</strong></td>
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<td></td>
<td></td>
<td>24.84</td>
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**PROMETHAZINE**

<table>
<thead>
<tr>
<th>Prescriber Bag</th>
<th>3488N</th>
<th>promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
<td>2</td>
<td><strong>DPMQ $</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>*35.60</td>
</tr>
</tbody>
</table>
### SALBUTAMOL

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3497C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>16.23</td>
<td>APO-Salbutamol [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Salbutamol AN [ED]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Asmol 5 uni-dose [AF]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11088N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>16.49</td>
<td>Ventolin Nebules [GK]</td>
</tr>
</tbody>
</table>

### SALBUTAMOL

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3496B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>16.02</td>
<td>APO-Salbutamol [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Salbutamol AN [ED]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Asmol 2.5 uni-dose [AF]</td>
</tr>
</tbody>
</table>

### TRAMADOL

**tramadol hydrochloride 100 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>
</tr>
</thead>
<tbody>
<tr>
<td>3484J</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>14.87</td>
<td>Tramadol ACT [JO]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tramadol Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tramadol AN [JU]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tramal 100 [CS]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>12108G</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>16.85</td>
<td>Asmol CFC-Free with dose counter [AF]</td>
</tr>
<tr>
<td></td>
<td>19.35</td>
<td>Ventolin CFC-Free with dose counter [GK]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3495Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>16.21</td>
<td>Asmol CFC-free [AL]</td>
</tr>
<tr>
<td></td>
<td>18.04</td>
<td>Ventolin CFC-free [GK]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11125M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>16.36</td>
<td>Ventolin Nebules [GK]</td>
</tr>
</tbody>
</table>
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ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

Antiinfectives and antiseptics for local oral treatment

AMPHOTERICIN B

amphotericin B 10 mg lozenge, 20

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
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<td>Fungilin [AS]</td>
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amphotericin B 10 mg lozenge, 20

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<td>..</td>
<td>16.28</td>
<td>17.57</td>
<td>Fungilin [AS]</td>
</tr>
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</table>

Other agents for local oral treatment

BENZODYAMINE

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

benzydamine hydrochloride 0.15% mouthwash, 500 mL

<table>
<thead>
<tr>
<th>Max Qty</th>
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<td>Difflam [IL]</td>
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BENZODYAMINE

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

benzydamine hydrochloride 0.15% mouthwash, 500 mL

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<td>Difflam [IL]</td>
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DRUGS FOR ACID RELATED DISORDERS

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.

cimetidine 400 mg tablet, 60

<table>
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FAMOTIDINE

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

famotidine 20 mg tablet, 60

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<th>Max Qty</th>
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<td></td>
<td></td>
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famotidine 40 mg tablet, 30

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<td>17.16</td>
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<td></td>
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<td>* GenRx Famotidine [GX]</td>
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<td></td>
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<td>* Famotidine AN [EA]</td>
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</table>

NIZATIDINE

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

**ALIMENTARY TRACT AND METABOLISM**

**Proton pump inhibitors**

### ESOMEPRAZOLE

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

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Standard dose proton pump inhibitors are appropriate step-down therapy from high dose proton pump inhibitors.

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

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

**Authority required**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
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<th>MRVSN $</th>
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**Authority required**

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**Clinical criteria:**

- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

**Authority required**

- **RANITIDINE**

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

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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**Proton pump inhibitors**

### RANITIDINE

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

**Note** Standard dose proton pump inhibitors are appropriate step-down therapy from high dose proton pump inhibitors.

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

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

**Authority required**

Gastro-oesophageal reflux disease

**Clinical criteria:**

- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

<table>
<thead>
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<th>Brand Name and Manufacturer</th>
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Scleroderma oesophagus

**Clinical criteria:**
- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

### esomeprazole 40 mg enteric capsule, 30

<table>
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<td>* Noxicid Caps [AL]</td>
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### esomeprazole 40 mg enteric tablet, 30

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<td>* Nexazole [RW]</td>
<td>* Nexole [RF]</td>
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### ESOMEPRAZOLE

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

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

**Authority required (STREAMLINED)**

**8780**

Scleroderma oesophagus

**Authority required (STREAMLINED)**

**8827**

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

### esomeprazole 20 mg enteric capsule, 30

<table>
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<tr>
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<td>* Nexazole [RW]</td>
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**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

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

**Authority required (STREAMLINED)**

**8776**

Gastro-oesophageal reflux disease

**Clinical criteria:**
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

### esomeprazole 20 mg enteric capsule, 30

<table>
<thead>
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### esomeprazole 20 mg enteric tablet, 30

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<tr>
<td></td>
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<td>* Esomeprazole RBX [RA]</td>
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<td>* Esomeprazole SZ [HX]</td>
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<td></td>
<td></td>
<td>* Nexazole [RW]</td>
<td>* Nexole [RF]</td>
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■ ESOMEPRAZOLE

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

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

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

Authority required (STREAMLINED)

8775
Peptic ulcer
Treatment Phase: Initial treatment
Clinical criteria:
- Patient must have tested negative for helicobacter pylori infection; OR
- Patient must have failed treatment with helicobacter pylori eradication therapy.

Authority required (STREAMLINED)

8774
Gastro-oesophageal reflux disease
Clinical criteria:
- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

■ LANSOPRAZOLE

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Restricted benefit
Gastro-oesophageal reflux disease

Restricted benefit
Scleroderma oesophagus

■ LANSOPRAZOLE

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.

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

Authority required (STREAMLINED)

8780
Scleroderma oesophagus

REFERENCE
LANSOPRAZOLE

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

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

Authority required (STREAMLINED)

8776 Gastro-oesophageal reflux disease

Clinical criteria:
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

LANSOPRAZOLE

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.

Note Check patient adherence to lower dose proton pump inhibitor before “stepping-up” therapy.

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

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

Authority required (STREAMLINED)

8775 Peptic ulcer

Treatment Phase: Initial treatment

Clinical criteria:
- Patient must have tested negative for helicobacter pylori infection; OR
- Patient must have failed treatment with helicobacter pylori eradication therapy.

Authority required (STREAMLINED)

8774 Gastro-oesophageal reflux disease

Clinical criteria:
- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.
**ALIMENTARY TRACT AND METABOLISM**

- **OMEPRAZOLE**

  **Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

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

**Omeprazole 10 mg enteric tablet, 30**

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**Omeprazole 20 mg enteric tablet, 30**

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**Omeprazole 20 mg enteric capsule, 30**

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</table>

**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.

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Authority required (STREAMLINED)**

- 8780 Scleroderma oesophagus

**Omeprazole 20 mg enteric capsule, 30**

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<td>Losec Tablets [AP]</td>
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ALIMENTARY TRACT AND METABOLISM

OMEPRAZOLE

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

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

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

Authority required (STREAMLINED) 8775 Peptic ulcer Treatment Phase: Initial treatment Clinical criteria:
• Patient must have tested negative for helicobacter pylori infection; OR
• Patient must have failed treatment with helicobacter pylori eradication therapy.

Authority required (STREAMLINED) 8774 Gastro-oesophageal reflux disease Clinical criteria:
• The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR
• The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

PANTOPRAZOLE

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

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

PANTOPRAZOLE

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

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

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

---

**Authority required (STREAMLINED)**

8780

Scleroderma oesophagus

---

**Authority required (STREAMLINED)**

8866

Zoller-Ellison syndrome

---

**PANTOPRAZOLE**

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

---

**PANTOPRAZOLE**

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**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

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**Note** No increase in the maximum number of repeats may be authorised.
### ALIMENTARY TRACT AND METABOLISM

**General Pharmaceutical Benefits**

**8775**
Peptic ulcer
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have tested negative for helicobacter pylori infection; OR
- Patient must have failed treatment with helicobacter pylori eradication therapy.

**Authority required (STREAMLINED)**

**8774**
Gastro-oesophageal reflux disease

**Clinical criteria:**
- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

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

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#### pantoprazole 40 mg enteric tablet, 30

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### RABEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Restricted benefit**
Gastro-oesophageal reflux disease

**Scleroderma oesophagus**

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

<table>
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<td>Rabeprazole Sandoz [SZ]</td>
</tr>
</tbody>
</table>

#### RABEPRAZOLE

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

**Note** Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

**Note** A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

**Authority required (STREAMLINED)**

**8780**
Scleroderma oesophagus

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

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<td>Zabep [AL]</td>
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</table>

**Note** Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

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

**Authority required (STREAMLINED)**

**8776**
Gastro-oesophageal reflux disease
Clinical criteria:
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

rabeprazole sodium 20 mg enteric tablet, 30

<table>
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<tr>
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<td>* Zabep [AL]</td>
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</table>

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

**Authority required (STREAMLINED)**

**8775**
Peptic ulcer
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have tested negative for helicobacter pylori infection; OR
- Patient must have failed treatment with helicobacter pylori eradication therapy.

**Authority required (STREAMLINED)**

**8774**
Gastro-oesophageal reflux disease

**Clinical criteria:**
- The treatment must be for initial treatment of symptomatic gastro-oesophageal reflux disease; OR
- The treatment must be for the short-term maintenance treatment of gastro-oesophageal reflux disease.

rabeprazole sodium 20 mg enteric tablet, 30

<table>
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<td>* Zabep [AL]</td>
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</table>

**Combinations for eradication of Helicobacter pylori**

**ESOMEPRAZOLE (&) CLARITHROMYCIN (&) AMOXICILLIN**

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

**Restricted benefit**
Eradication of Helicobacter pylori

**Clinical criteria:**
- The condition must be associated with peptic ulcer disease.

esomeprazole 20 mg enteric tablet [14] (&) amoxicillin 500 mg capsule [28] (&) clarithromycin 500 mg tablet [14], 1 pack

<table>
<thead>
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<th>Max Qty Packs</th>
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esomeprazole 20 mg enteric tablet [14] (&) amoxicillin 500 mg capsule [28] (&) clarithromycin 500 mg tablet [14], 1 pack

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

**SUCRALFATE**

Sucralfate 1 g tablet, 120

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BELLADONNA AND DERIVATIVES, PLAIN
Belladonna alkaloids, tertiary amines

ATROPINE SULFATE

atropine sulfate monohydrate 600 microgram/mL injection, 10 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>Pfizer Australia Pty Ltd [PF]</td>
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ATROPINE SULFATE

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.

PROPULSIVES

DOMPERIDONE

domperidone 10 mg tablet, 25

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<tr>
<td>Motilium [JC]</td>
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METOCLOPRAMIDE

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

<table>
<thead>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>Maxolon [IL]</td>
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metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules

<table>
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<td>Maxolon [IL]</td>
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metoclopramide hydrochloride 10 mg tablet, 25

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<td>Pramin [AF]</td>
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ANTIMETHEMICS AND ANTINAUSEANTS

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.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<tr>
<td>Granisetron Kabi [PK]</td>
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<td>Granisetron Kabi [PK]</td>
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GRANISETRON 3 mg/3 mL injection, 3 mL ampoule

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<tr>
<td>Granisetron Kabi [PK]</td>
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<td>Granisetron Kabi [PK]</td>
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ALIMENTARY TRACT AND METABOLISM

### GRANISETRON

**Authority required (STREAMLINED)**

**4092**

Nausea and vomiting

**Clinical criteria:**

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

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### GRANISETRON

**Authority required (STREAMLINED)**

**10498**

Nausea and vomiting

**Clinical criteria:**

- The condition must be associated with radiotherapy being used to treat malignancy; OR
- The condition must be associated with oral chemotherapy being used to treat malignancy.

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### GRANISETRON

**Restricted benefit**

Nausea and vomiting

**Clinical criteria:**

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

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

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### NETUPITANT + PALONOSETRON

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

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

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

**Authority required (STREAMLINED)**

**5991**

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 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 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

**Authority required (STREAMLINED)**

**5994**

Nausea and vomiting

**Clinical criteria:**

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

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

**Authority required (STREAMLINED)**

**6937**

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 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; 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; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination 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 dexamethasone on day 1 of a chemotherapy cycle, AND
• Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.

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

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

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**ONDANSETRON**

**Authority required (STREAMLINED)**

**Nausea and vomiting**

**Clinical criteria:**
• The condition must be associated with radiotherapy being used to treat malignancy; OR
• The condition must be associated with oral chemotherapy being used to treat malignancy.

**ondansetron 4 mg tablet, 10**

<table>
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**ondansetron 8 mg tablet, 10**

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<td>Ondansetron Mylan Tablets [AF]</td>
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<td>Zofran [AS]</td>
</tr>
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</table>

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**ONDANSETRON**

**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.

**ondansetron 4 mg tablet, 4**

<table>
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**ondansetron 8 mg tablet, 4**

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<td></td>
<td>Zofran [AS]</td>
</tr>
</tbody>
</table>
**ONDANSETRON**

**Authority required (STREAMLINED)**

4102

Nausea and vomiting

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

ondansetron 4 mg/5 mL oral liquid, 50 mL

Max Qty | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
--- | --- | --- | --- | --- | ---
1 | 1 | .. | 98.87 | 41.00 | Zofran syrup 50 mL [AS]

**ONDANSETRON**

**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.

ondansetron 4 mg/5 mL oral liquid, 50 mL

Max Qty | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
--- | --- | --- | --- | --- | ---
1 | .. | .. | 98.87 | 41.00 | Zofran syrup 50 mL [AS]

**ONDANSETRON**

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

**Authority required (STREAMLINED)**

10498

Nausea and vomiting

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

ondansetron 4 mg orally disintegrating tablet, 10

Max Qty | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
--- | --- | --- | --- | --- | ---
1 | 1 | .. | 21.19 | 22.48 | *
- APO-Ondansetron ODT [TX]
- Ondansetron Mylan ODT [AF]
- Ondansetron ODT GH [GQ]
- Zilfojim ODT 4 [DO]
- Ondansetron AN ODT [EA]
- Ondansetron ODT-DRLA [RZ]
- Ondansetron SZ ODT [HX]
- Zofran Zydis [AS]
- Zotren ODT [RF]

ondansetron 4 mg wafer, 10

Max Qty | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
--- | --- | --- | --- | --- | ---
1 | 1 | 2.45 | 23.64 | 22.48 | *
- Zofran Zydis [AS]

**ONDANSETRON**

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

**Authority required (STREAMLINED)**

10498

Nausea and vomiting

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

ondansetron 8 mg orally disintegrating tablet, 10

Max Qty | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
--- | --- | --- | --- | --- | ---
1 | 1 | .. | 26.41 | 27.70 | *
- APO-Ondansetron ODT [TX]
- Ondansetron Mylan ODT [AF]
- Ondansetron ODT GH [GQ]
- Zilfojim ODT 8 [DO]
- Ondansetron AN ODT [EA]
- Ondansetron ODT-DRLA [RZ]
- Ondansetron SZ ODT [HX]
- Zotren ODT [RF]

ondansetron 8 mg wafer, 10

Max Qty | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
--- | --- | --- | --- | --- | ---
1 | 1 | 2.45 | 28.86 | 27.70 | *
- Zofran Zydis [AS]

**ONDANSETRON**

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

**General Pharmaceutical Benefits**

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

### 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.

### ondansetron 4 mg orally disintegrating tablet, 4

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### ondansetron 8 mg orally disintegrating tablet, 4

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### ondansetron 4 mg wafer, 4

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<td>Zofran Zydis [AS]</td>
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### ondansetron 8 mg wafer, 4

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</table>

### PALONOSETRON

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

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

**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.

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

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</tr>
</thead>
<tbody>
<tr>
<td>5295Q</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

### TROPISETRON

**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.

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
<tr>
<td>2746M</td>
<td></td>
<td>16.93</td>
<td>18.22</td>
<td></td>
<td>Tropisetron-AFT [AE]</td>
</tr>
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</table>

**Other antiemetics**

### APREPITANT

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

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

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

**Authority required (STREAMLINED)**

<table>
<thead>
<tr>
<th>4211</th>
<th>Nausea and vomiting</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

**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: altretamin; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose.
of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

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

Authority required (STREAMLINED)

4215
Nausea and vomiting
Clinical criteria:
- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, AND
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, AND
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

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

Authority required (STREAMLINED)

6444
Nausea and vomiting
Clinical criteria:
- The condition must be associated with moderate 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 either carboplatin or oxaliplatin.

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

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

Authority required (STREAMLINED)

6370
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 on day 1 of a chemotherapy cycle, AND
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.

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

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

Authority required (STREAMLINED)

6886
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 either carboplatin or oxaliplatin.

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

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

Authority required (STREAMLINED)

6891
Nausea and vomiting
Clinical criteria:
- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, AND
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, AND
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

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

Authority required (STREAMLINED)

6887
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; 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; daclomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.

**Authority required (STREAMLINED) 6852**

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 on day 1 of a chemotherapy cycle, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy. Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.

**fosaprepitant 150 mg injection, 1 vial 11107N**

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<td>116.71</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 mesilate 12.5 mg/mL injection, 10 x 1 mL ampoules 5206B**

<table>
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**prochlorperazine maleate 5 mg tablet, 25 5205Y**

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<td></td>
<td>* Stemzine [AV]</td>
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<td>a3.00</td>
<td>15.99</td>
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</table>

**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 mesilate 12.5 mg/mL injection, 10 x 1 mL ampoules 2369Q**

<table>
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<tr>
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<td>21.70</td>
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<td>Stemetil [SW]</td>
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**prochlorperazine maleate 5 mg tablet, 25 2839G**

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<td>a3.00</td>
<td>15.99</td>
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**PROMETHAZINE**

**promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules 3374N**

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<tr>
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BILE AND LIVER THERAPY

BILE THERAPY

Bile acids and derivatives

URSODEOXYCHOLIC ACID

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

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

Authority required (STREAMLINED)
9032
Primary biliary cholangitis (previously known as Primary biliary cirrhosis)

урсодексохолевая кислота 250 мг капсула, 100

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

NP 2 2 .. *226.32 41.00 * APO-Ursodeoxycholic acid [TX]
* Ursodox GH [GQ]
* Ursosan [BZ]

урсодексохолевая кислота 500 мг таблетка, 100

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

NP 1 2 .. 294.91 41.00 Ursofalk [FD]

DRUGS FOR CONSTIPATION

Contact laxatives

BISACODYL

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

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

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

Restricted benefit
Constipation
Clinical criteria:
- Patient must be receiving palliative care.

Restricted benefit
Terminal malignant neoplasia

Restricted benefit
Anorectal congenital abnormalities

Restricted benefit
Megacolon

bisacodyl 5 mg enteric tablet, 200

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

NP 1 2 .. 18.01 19.30 Lax-Tab [AE]

BISACODYL

Restricted benefit
Constipation
Clinical criteria:
- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.
• Patient must be receiving palliative care.

**Restricted benefit**

**Constipation**

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

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

**Restricted benefit**

**Constipation**

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

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

**Restricted benefit**

**Terminal malignant neoplasia**

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

**Restricted benefit**

**Anorectal congenital abnormalities**

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

**Restricted benefit**

**Megacolon**

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

---

**bisacodyl 10 mg suppository, 10**

<table>
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<tr>
<td>1260H</td>
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<td>*24.66</td>
<td>25.95</td>
<td>* Petrus Bisacodyl Suppositories [PP]</td>
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**bisacodyl 10 mg suppository, 12**

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<td>1258F</td>
<td>3</td>
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<td>*22.38</td>
<td>23.67</td>
<td>Petrus Bisacodyl Suppositories [PP]</td>
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---

**Bulk-forming laxatives**

- **RHAMNUS FRANGULA + STERCULIA**

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Terminal malignant neoplasia**

**Restricted benefit**

**Anorectal congenital abnormalities**

**Restricted benefit**

**Megacolon**
### Osmotically acting laxatives

#### MACROGOL-3350

<table>
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<tr>
<th>Restricted benefit</th>
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<tbody>
<tr>
<td>Clinical criteria:</td>
<td>• Patient must have malignant neoplasia.</td>
</tr>
<tr>
<td>Restricted benefit</td>
<td>Constipation</td>
</tr>
<tr>
<td>Clinical criteria:</td>
<td>• Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, AND</td>
</tr>
<tr>
<td>Restricted benefit</td>
<td>The condition must be unresponsive to other oral therapies.</td>
</tr>
<tr>
<td>Clinical criteria:</td>
<td>• The condition must be inadequately controlled with first line interventions such as bulk-forming agents.</td>
</tr>
<tr>
<td>Clinical criteria:</td>
<td>• The condition must be inadequately controlled with first line interventions such as bulk-forming agents.</td>
</tr>
<tr>
<td>macrogol-3350 1 g/g powder for oral liquid, 510 g</td>
<td>3416T</td>
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<tr>
<td>Max Qty Packs</td>
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<tr>
<td>1</td>
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</table>

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

<table>
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<tbody>
<tr>
<td>Clinical criteria:</td>
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<td>Constipation</td>
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<td>Clinical criteria:</td>
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<td>The condition must be unresponsive to other oral therapies.</td>
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<tr>
<td>Clinical criteria:</td>
<td>• The condition must be inadequately controlled with first line interventions such as bulk-forming agents.</td>
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<tr>
<td>Clinical criteria:</td>
<td>• The condition must be inadequately controlled with first line interventions such as bulk-forming agents.</td>
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<tr>
<td>macrogol-3350 13.125 g/25 mL + sodium chloride 350.7 mg/25 mL + sodium bicarbonate 178.5 mg/25 mL + potassium chloride 46.6 mg/25 mL oral liquid, 500 mL</td>
<td>10126Y</td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
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<tr>
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#### MACROGOL-3350 13.125 g + sodium chloride 350.7 mg + sodium bicarbonate 178.5 mg + potassium chloride 46.6 mg powder for oral liquid, 30 sachets | 8612G |
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<td>19.59</td>
<td>20.88</td>
<td>* APOHEALTH Macrogol with Electrolytes [GX]</td>
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<td>* Chemists’ Own Macrogol with Electrolytes [RW]</td>
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<td></td>
<td></td>
<td>* APO-MACROGOL plus ELECTROLYTES [TX]</td>
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<td></td>
<td></td>
<td>* LaxaCon [EA]</td>
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</tbody>
</table>
**Enemas**

- **BISACODYL**

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Constipation**

**Clinical criteria:**
- Patient must be 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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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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- **CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL**

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Constipation**

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

**Restricted benefit**

**Terminal malignant neoplasia**

**Restricted benefit**

**Anorectal congenital abnormalities**

**Restricted benefit**

**Megacolon**

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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### ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTION AGENTS

#### INTESTINAL ANTIINFECTIVES

**Antibiotics**

##### NYSTATIN

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<table>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>...</td>
<td>...</td>
<td>21.19</td>
<td>22.48</td>
<td></td>
<td>Nilstat [AS]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nystatin 500 000 units tablet, 50 1696G</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>1</td>
<td>...</td>
<td>...</td>
<td>21.19</td>
<td>22.48</td>
<td></td>
<td>Nilstat [AS]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nystatin 500 000 units tablet, 50 3342X</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>1</td>
<td>...</td>
<td>...</td>
<td>21.19</td>
<td>22.48</td>
<td></td>
<td>Nilstat [AS]</td>
</tr>
</tbody>
</table>

##### RIFAXIMIN

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

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

**Authority required**

Prevention of hepatic encephalopathy

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

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

<table>
<thead>
<tr>
<th>Rifaximin 550 mg tablet, 56 10001J</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>1</td>
<td>5</td>
<td>...</td>
<td>475.40</td>
<td>41.00</td>
<td></td>
<td>Xifaxan [NE]</td>
</tr>
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</table>

##### VANCOMYCIN

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

**Authority required**

Antibiotic associated pseudomembranous colitis

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

**Authority required**

Antibiotic associated pseudomembranous colitis

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

<table>
<thead>
<tr>
<th>Vancomycin 125 mg capsule, 20 3113W</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>
<td>...</td>
<td>*225.26</td>
<td>41.00</td>
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<td>Vancocin [AS]</td>
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</table>

<table>
<thead>
<tr>
<th>Vancomycin 250 mg capsule, 20 3114X</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>2</td>
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<td>...</td>
<td>*443.42</td>
<td>41.00</td>
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<td>Vancocin [AS]</td>
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</table>

### ELECTROLYTES WITH CARBOHYDRATES

**Oral rehydration salt formulations**

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

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander.
sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 g sachets

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

**Authority required**
Rehydration in intestinal failure

sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 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>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>16.83</td>
<td>18.12</td>
<td>* O.R.S. [AF]</td>
<td>* restore O.R.S. [EA]</td>
</tr>
</tbody>
</table>

### ANTIPROPULSIVES

**Antipropulsives**

### DIPHENOXYLATE + ATROPINE SULFATE

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

<table>
<thead>
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<th>Premium $</th>
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<th>MRVSN $</th>
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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>13.80</td>
<td>15.09</td>
<td>* Lofenoxal [IL]</td>
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</tr>
<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>15.31</td>
<td>15.09</td>
<td>* Lomotil [IM]</td>
<td></td>
</tr>
</tbody>
</table>

### LOPERAMIDE

**Authority required (STREAMLINED)**

**6364**
Diarrhoea

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

loperamide hydrochloride 2 mg capsule, 12

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>13.51</td>
<td>14.80</td>
<td>* Gastrex [CR]</td>
<td>* Gastro-Stop [AS]</td>
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</tbody>
</table>

### INTESTINAL ANTIINFLAMMATORY AGENTS

**Corticosteroids acting locally**

### BUDENOSIDE

**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

<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>3</td>
<td>166.42</td>
<td>41.00</td>
<td></td>
<td>Budenofalk [FD]</td>
<td></td>
</tr>
</tbody>
</table>

### HYDROCORTISONE 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.

hydrocortisone acetate 10% enema, 21.1 g

<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>2</td>
<td>3</td>
<td>*41.60</td>
<td>41.00</td>
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<td>Colifoam [GO]</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.

<table>
<thead>
<tr>
<th>Prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty</strong></td>
</tr>
<tr>
<td>1920C</td>
</tr>
</tbody>
</table>

**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>Prednisolone (as sodium phosphate) 5 mg suppository, 10</th>
</tr>
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<tbody>
<tr>
<td><strong>Max Qty</strong></td>
</tr>
<tr>
<td>2554K</td>
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</tbody>
</table>

### Aminosalicylic acid and similar agents

### BALSALAZIDE

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

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

**Authority required (STREAMLINED)**

7621
Ulcereative colitis

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

<table>
<thead>
<tr>
<th>Balsalazide sodium 750 mg capsule, 280</th>
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<tbody>
<tr>
<td><strong>Max Qty</strong></td>
</tr>
<tr>
<td>11351K</td>
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</table>

### MESALAZINE

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

**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.

**Restricted benefit**
Ulcereative colitis

<table>
<thead>
<tr>
<th>Mesalazine 4 g modified release granules, 30 sachets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty</strong></td>
</tr>
<tr>
<td>10254Q</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mesalazine 1 g modified release granules, 100 sachets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty</strong></td>
</tr>
<tr>
<td>8599N</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mesalazine 1.5 g modified release granules, 60 sachets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty</strong></td>
</tr>
<tr>
<td>9206M</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mesalazine 500 mg modified release granules, 100 sachets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty</strong></td>
</tr>
<tr>
<td>8598M</td>
</tr>
</tbody>
</table>
### MESALAZINE

**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.

**Restricted benefit**
Ulcerative colitis

**Restricted benefit**
Crohn disease

---

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Maximum Quantity</th>
<th>Number of Months</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>Salofalk [FD]</td>
<td>30</td>
<td>1</td>
<td>116.71</td>
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<td>60</td>
<td>2</td>
<td>195.22</td>
<td>41.00</td>
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<tr>
<td>Mesasal [GO]</td>
<td>100</td>
<td>1</td>
<td>107.99</td>
<td>41.00</td>
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<tr>
<td>Pentasa [FP]</td>
<td>60</td>
<td>1</td>
<td>133.25</td>
<td>41.00</td>
</tr>
<tr>
<td>Pentasa [FP]</td>
<td>60</td>
<td>2</td>
<td>150.66</td>
<td>41.00</td>
</tr>
<tr>
<td>Pentasa [FP]</td>
<td>100</td>
<td>1</td>
<td>158.52</td>
<td>41.00</td>
</tr>
<tr>
<td>Pentasa [FP]</td>
<td>100</td>
<td>2</td>
<td>150.66</td>
<td>41.00</td>
</tr>
<tr>
<td>Salofalk [FD]</td>
<td>100</td>
<td>1</td>
<td>140.86</td>
<td>41.00</td>
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<tr>
<td>Salofalk [FD]</td>
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<td>140.86</td>
<td>41.00</td>
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<tr>
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<td>140.86</td>
<td>41.00</td>
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<tr>
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<td>2</td>
<td>140.86</td>
<td>41.00</td>
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</table>

---

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

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

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

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

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

---

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Maximum Quantity</th>
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<th>MRVSN</th>
</tr>
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<tbody>
<tr>
<td>Salofalk [FD]</td>
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<td>1</td>
<td>107.99</td>
<td>41.00</td>
</tr>
<tr>
<td>Salofalk [FD]</td>
<td>30</td>
<td>2</td>
<td>158.52</td>
<td>41.00</td>
</tr>
<tr>
<td>Salofalk [FD]</td>
<td>30</td>
<td>1</td>
<td>140.86</td>
<td>41.00</td>
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</tbody>
</table>
mesalazine 1 g suppository, 28

<table>
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<tr>
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<th>DPMQ</th>
<th>MRVSN</th>
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<tr>
<td>12198B</td>
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<td>Pentasa [FP]</td>
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</tbody>
</table>

**MESALAZINE**

**Note** Not for the treatment of Crohn disease
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Note Continuing Therapy Only:**
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**Authority required (STREAMLINED)**

**4888**
Acute episode of mild to moderate ulcerative colitis

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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<td>8753Q</td>
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<td>Pentasa [FP]</td>
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</table>

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

<table>
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<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<td>*272.98</td>
<td>41.00</td>
<td>Salofalk [FD]</td>
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</table>

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

<table>
<thead>
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<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
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<td>8617M</td>
<td>4</td>
<td>..</td>
<td>*366.50</td>
<td>41.00</td>
<td>Salofalk [FD]</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>
<th>MRVSN</th>
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<td>..</td>
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<td>41.00</td>
<td>Salofalk [FD]</td>
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</tbody>
</table>

**OLSALAZINE**

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

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

**Authority required (STREAMLINED)**

**4824**
Ulcerative colitis

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

olsalazine sodium 250 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>
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<td>1728Y</td>
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<td>5</td>
<td>52.63</td>
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<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>
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<td>5</td>
<td>83.55</td>
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<td>Dipentum [IX]</td>
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</table>

**SULFASALAZINE**

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

sulfasalazine 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>
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<td>2093E</td>
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<td>Salazopyrin [PF]</td>
</tr>
</tbody>
</table>

sulfasalazine 500 mg enteric 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>
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<td>5</td>
<td>*55.36</td>
<td>41.00</td>
<td>Pyralin EN [FZ]</td>
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<tr>
<td>^4.00</td>
<td>59.36</td>
<td>41.00</td>
<td>Salazopyrin-EN [PF]</td>
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<td></td>
</tr>
</tbody>
</table>
### SULFASALAZINE

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

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

**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.

<table>
<thead>
<tr>
<th>Sulfasalazine 500 mg tablet, 100</th>
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</thead>
<tbody>
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<td>9208P</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sulfasalazine 500 mg enteric tablet, 100</th>
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</thead>
<tbody>
<tr>
<td>9209Q</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2</td>
</tr>
</tbody>
</table>

### 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.

<table>
<thead>
<tr>
<th>Pancreatic extract 10 000 units modified release capsule, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>8020D</td>
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<tr>
<td>Max Qty Packs</td>
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<table>
<thead>
<tr>
<th>Pancreatic extract 25 000 units modified release capsule, 100</th>
</tr>
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<tbody>
<tr>
<td>8021E</td>
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<tr>
<td>Max Qty Packs</td>
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<tr>
<td>2</td>
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<table>
<thead>
<tr>
<th>Pancreatic extract 40 000 units modified release capsule, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>9412J</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pancreatic extract 5000 units/100 mg enteric coated granules, 20 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>5453B</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>

### PANCREATIC EXTRACT

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

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

**Restricted benefit**

Cystic fibrosis

**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.

<table>
<thead>
<tr>
<th>Pancreatic extract 10 000 units modified release capsule, 100</th>
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<tbody>
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<td>Max Qty Packs</td>
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<table>
<thead>
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<th>Pancreatic extract 25 000 units modified release capsule, 100</th>
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<td>Max Qty Packs</td>
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<table>
<thead>
<tr>
<th>Pancreatic extract 40 000 units modified release capsule, 100</th>
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</thead>
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<tr>
<td>Max Qty Packs</td>
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<table>
<thead>
<tr>
<th>Pancreatic extract 5000 units/100 mg enteric coated granules, 20 g</th>
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</thead>
<tbody>
<tr>
<td>5454C</td>
</tr>
<tr>
<td>Max Qty Packs</td>
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<tr>
<td>3</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.

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

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

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

**Restricted benefit**
Cystic fibrosis

<table>
<thead>
<tr>
<th>Clinical criteria:</th>
</tr>
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<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

### DRUGS USED IN DIABETES

#### INSULINS AND ANALOGUES

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

### INSULIN ASPART

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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</thead>
<tbody>
<tr>
<td>NovoRapid [NO]</td>
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<td>5</td>
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<tr>
<td>NovoRapid FlexPen [NF]</td>
<td></td>
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<td>5</td>
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<tr>
<td>NovoRapid Penfill 3 mL [NO]</td>
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<td></td>
<td>5</td>
<td>1</td>
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<tr>
<td>Fiasp [NO]</td>
<td></td>
<td></td>
<td></td>
<td>5</td>
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<tr>
<td>Fiasp FlexTouch [NO]</td>
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<td>5</td>
<td>1</td>
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</table>

### INSULIN GLULISINE

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<th>MRVSN $</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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</thead>
<tbody>
<tr>
<td>Apidra [AV]</td>
<td></td>
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<tr>
<td>Apidra SoloStar [SW]</td>
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</tbody>
</table>

### INSULIN LISPRO

<table>
<thead>
<tr>
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<th>MRVSN $</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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</thead>
<tbody>
<tr>
<td>Humalog [LY]</td>
<td></td>
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<tr>
<td>Humalog KwikPen [KP]</td>
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</tr>
<tr>
<td>Humalog U200 Kwikpen [LY]</td>
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<td></td>
<td>5</td>
<td>1</td>
</tr>
</tbody>
</table>
INSULIN NEUTRAL HUMAN
insulin neutral human 100 units/mL injection, 1 x 10 mL vial
1531N

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
5 2 .. *106.09 41.00 Actrapid [NO] Humulin R [LY]

insulin neutral human 100 units/mL injection, 5 x 3 mL cartridges
1762R

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
5 1 .. *177.49 41.00 Actrapid Penfill 3 mL [NO] Humulin R [LY]

INSULINS AND ANALOGUES FOR INJECTION

INSULIN ISOPHANE HUMAN
insulin isophane human 100 units/mL injection, 1 x 10 mL vial
1533Q

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
5 2 .. *106.09 41.00 Humulin NPH [LY] Protaphane [NO]

insulin isophane human 100 units/mL injection, 5 x 3 mL cartridges
1761Q

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
5 1 .. *177.49 41.00 Humulin NPH [LY] Protaphane Penfill 3 mL [NO] Protaphane InnoLet [NI]

INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING

INSULIN ASPART + INSULIN ASPART PROTAMINE
insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL syringes
8609D

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
5 1 .. *211.49 41.00 NovoMix 30 FlexPen [NF] NovoMix 30 Penfill 3 mL [NO]

INSULIN DEGLUDEC + INSULIN ASPART
Note Special Pricing Arrangements apply.

insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL pen devices
11417X

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
5 1 .. *379.54 41.00 Ryzodeg Flextouch [NO]

insulin degludec 70 units/mL + insulin aspart 30 units/mL injection, 5 x 3 mL cartridges
11426J

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
5 1 .. *379.54 41.00 Ryzodeg Penfill [NO]

INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN
insulin neutral human 50 units/mL + insulin isophane human 50 units/mL injection, 5 x 3 mL cartridges
2062M

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
5 1 .. *185.84 41.00 Mixtard 50/50 Penfill 3 mL [NO]

insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 1 x 10 mL vial
1426C

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
5 2 .. *106.09 41.00 Humulin 30/70 [LY]

insulin isophane human 70 units/mL + insulin neutral human 30 units/mL injection, 5 x 3 mL cartridges
1763T

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
5 1 .. *177.49 41.00 Humulin 30/70 [LY] Mixtard 30/70 [NI]

INSULIN LISPRO + INSULIN LISPRO PROTAMINE
insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL cartridges
8390N

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
5 1 .. *211.49 41.00 Humalog Mix25 [LY] Humalog Mix25 KwikPen [KP]

insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL cartridges
8874C

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
5 1 .. *211.49 41.00 Humalog Mix50 [LY] Humalog Mix50 KwikPen [KP]

INSULIN DETEMIR
Note Special Pricing Arrangements apply.
### Restricted benefit

**Type 1 diabetes**

<table>
<thead>
<tr>
<th>Insulin detemir 100 units/mL injection, 5 x 3 mL cartridges</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>9040T</strong>&lt;br&gt;Max Qty Packs</td>
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<tr>
<td>5</td>
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</tbody>
</table>

**INSULIN GLARGINE**

**Note** Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Insulin glargine 300 units/mL injection, 3 x 1.5 mL pen devices</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>11308E</strong>&lt;br&gt;Max Qty Packs</td>
</tr>
<tr>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Insulin glargine 300 units/mL injection, 5 x 1.5 mL pen devices</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>11301W</strong>&lt;br&gt;Max Qty Packs</td>
</tr>
<tr>
<td>5</td>
</tr>
</tbody>
</table>

**INSULIN GLARGINE**

**Note** Biosimilar prescribing policy

Prescribing of the biosimilar brand, Semglee, is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

**Note** Pharmaceutical benefits that have the brand Optisulin SoloStar 100 units/mL injection, 5 x 3 mL cartridges and pharmaceutical benefits that have the brand Semglee 100 units/mL injection, 5 x 3 mL pen devices are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
<th>Insulin glargine 100 units/mL injection, 5 x 3 mL cartridges</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>9039R</strong>&lt;br&gt;Max Qty Packs</td>
</tr>
<tr>
<td>5</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Insulin glargine 100 units/mL injection, 5 x 3 mL pen devices</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>11815W</strong>&lt;br&gt;Max Qty Packs</td>
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</table>

### BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

#### Biguanides

<table>
<thead>
<tr>
<th>Metformin hydrochloride 1 g tablet, 90</th>
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<tbody>
<tr>
<td><strong>8607B</strong>&lt;br&gt;Max Qty Packs</td>
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<tr>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Metformin hydrochloride 1 g modified release tablet, 60</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3439B</strong>&lt;br&gt;Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
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<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Metformin hydrochloride 500 mg tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2430X</strong>&lt;br&gt;Max Qty Packs</td>
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<tr>
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<table>
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<tr>
<th>Metformin hydrochloride 850 mg tablet, 60</th>
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<tr>
<td><strong>1801T</strong>&lt;br&gt;Max Qty Packs</td>
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<tr>
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<tr>
<td></td>
</tr>
</tbody>
</table>
**ALIMENTARY TRACT AND METABOLISM**

---

### METFORMIN

**Note**: Pharmaceutical benefits that have the form metformin hydrochloride 500 mg modified release tablet in a pack size of 120 can be substituted for a pack size of 56 in the case of a shortage.

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

<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>5</td>
<td>..</td>
<td>16.33</td>
<td>17.62</td>
<td>APO-Metformin XR 500 [TX]</td>
<td>Blooms the Chemist Metformin XR 500 [IB]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Metex XR [RW]</td>
<td>Metformin XR 500 APOTEX [GX]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td>Pharmacor Metformin XR [CR]</td>
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</tr>
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</table>

- 4.95

**metformin hydrochloride 500 mg modified release tablet, 56**

<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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<tr>
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<td>22.00</td>
<td>23.29</td>
<td>Metformin (Medsurge) [DZ]</td>
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</tbody>
</table>

### Sulfonylureas

#### GLIBENCLAMIDE

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

**glibenclamide 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>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>16.34</td>
<td>17.63</td>
<td>Daonil [SW]</td>
</tr>
</tbody>
</table>

### GLICLAZIDE

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

**gliclazide 30 mg modified release 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>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
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<td>18.05</td>
<td>19.34</td>
<td>APO-Gliclazide MR [TX]</td>
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<td>Pharmacor Gliclazide MR [CR]</td>
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<td>Glyade MR [AF]</td>
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**gliclazide 60 mg modified release tablet, 60**

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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>19.26</td>
<td>20.55</td>
<td>ARDI Gliclazide 60mg MR [RX]</td>
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<td></td>
<td></td>
<td>Pharmacor Gliclazide MR [CR]</td>
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</table>

- 7.62

**gliclazide 80 mg tablet, 100**

<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>17.88</td>
<td>19.17</td>
<td>APO-Gliclazide [TX]</td>
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<td></td>
<td>Glyade [AF]</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Nidem [RW]</td>
</tr>
</tbody>
</table>

### GLIMEPIRIDE

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

**glimepiride 1 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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<tr>
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<td>12.99</td>
<td>14.28</td>
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<td>Diapride 1 [RW]</td>
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<td>Glimepiride AN [EA]</td>
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<td></td>
<td>Glimepiride Sandoz [SZ]</td>
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<td>Aylide 1 [AF]</td>
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<td>Dimirel [AV]</td>
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<td>Glimepiride APOTEX [GX]</td>
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- 2.23

**glimepiride 2 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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<tr>
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**glimepiride 3 mg tablet, 30**

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ALIMENTARY TRACT AND METABOLISM

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

- **ALOGLIPTIN + METFORMIN**
  
  **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.

  **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
  
  The results of the 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.

- **DAPAGLIFLOZIN + METFORMIN**
  
  **Note** This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another SGLT2 inhibitor.

  **Note** PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or
  
  - a gliptin with a glitazone; or
  
  - an SGLT2 inhibitor with a glitazone.
ALIMENTARY TRACT AND METABOLISM

**Authority required (STREAMLINED) 7498**
Diabetes mellitus type 2
Treatment Phase: Initial treatment

**Clinical criteria:**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and a gliptin for this condition; **OR**
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, must be documented in the patient's medical records.

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### dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56

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### dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28

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### dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28

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### DAPAGLIFLOZIN + METFORMIN

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

---

**Authority required (STREAMLINED) 5631**
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.

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

---

**Authority required (STREAMLINED) 5739**
Diabetes mellitus type 2
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and dapagliflozin.
Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

**5798**
Diabetes mellitus type 2

**Clinical criteria:**
- 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 optimal doses of dual oral therapy; **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 despite treatment with optimal doses of dual oral therapy.

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.

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 fixed dose combination.

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

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

**Authority required (STREAMLINED)**

**5657**
Diabetes mellitus type 2

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

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

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

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

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

**Authority required (STREAMLINED)**

**7492**
Diabetes mellitus type 2

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), AND
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another SGLT2 inhibitor.

Note PBS-subsidised dual oral therapy does not include combination use of a gliptin with an SGLT2 inhibitor; or
- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.
**ALIMENTARY TRACT AND METABOLISM**

**General Pharmaceutical Benefits**

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**dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56**

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**dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28**

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**dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28**

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**EMPAGLIFLOZIN + LINAGLIPTIN**

**Note** This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

---

**Authority required (STREAMLINED)**

7524

Diabetes mellitus type 2

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a dipeptidyl peptidase 4 inhibitor (gliptin) or a sodium-glucose co-transporter 2 (SGLT2) inhibitor; **OR**
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient’s medical records at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin. The HbA1c must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin.

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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient’s medical records.

**empagliflozin 10 mg + linagliptin 5 mg tablet, 30**

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**empagliflozin 25 mg + linagliptin 5 mg tablet, 30**

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**EMPAGLIFLOZIN + LINAGLIPTIN**

**Note** This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 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.

---

**Authority required (STREAMLINED)**

7556

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

**empagliflozin 10 mg + linagliptin 5 mg tablet, 30**

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**ALIMENTARY TRACT AND METABOLISM**

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**EMPAGLIFLOZIN + METFORMIN**

**Authority required (STREAMLINED)**

**5953**

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 of treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (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 at 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**

- 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.

**Note**

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

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**empagliflozin 5 mg + linagliptin 5 mg tablet, 30**

**11298P**

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**empagliflozin 25 mg + linagliptin 5 mg tablet, 30**

**11299P**

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**empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 30**

**10650M**

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**empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60**

**10649L**

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**empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 30**

**10639Y**

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**empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60**

**10639Y**

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Schedule of Pharmaceutical Benefits – December 2020
**General Pharmaceutical Benefits**

**EMPAGLIFLOZIN + METFORMIN**

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

**Authority required (STREAMLINED)**

**5966**

- Diabetes mellitus type 2
- Treatment Phase: Continuing treatment
- **Clinical criteria:**
  - Patient must have previously received and been stabilised on a PBS subsidised regimen of oral diabetic medicines which includes metformin and empagliflozin.

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

**Authority required (STREAMLINED)**

**5798**

- Diabetes mellitus type 2
- **Clinical criteria:**
  - 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 optimal doses of dual oral therapy; **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 despite treatment with optimal doses of dual oral therapy.

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.

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

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

**Authority required (STREAMLINED)**

**5657**

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

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

**Note** This fixed dose combination is not PBS-subsidised for as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

7492

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

**Note** This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another SGLT2 inhibitor.

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

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**ERTUGLIFLOZIN + METFORMIN**

**Note** This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), insulin, a glucagon-like peptide-1 analogue, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

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

**Authority required (STREAMLINED)**

7498

Diabetes mellitus type 2

Treatment Phase: Initial treatment

**Clinical criteria:**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and a gliptin for this condition; **OR**
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient’s medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.
**ERTUGLIFLOZIN + METFORMIN**

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

### **Authority required (STREAMLINED)**

**5631**
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 an 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.

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

### **Authority required (STREAMLINED)**

**8249**
Diabetes mellitus type 2

**Treatment Phase: Continuing treatment**

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

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

### **Authority required (STREAMLINED)**

**7492**
Diabetes mellitus type 2

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), AND
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

**Note**
This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), insulin, a glucagon-like peptide-1 analogue, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

**Note**
PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or
- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.
ertugliflozin 2.5 mg + metformin hydrochloride 500 mg tablet, 56

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ertugliflozin 2.5 mg + metformin hydrochloride 1 g tablet, 56

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**ERTUGLIFLOZIN + SITAGLIPTIN**

**Note** This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

**Authority required (STREAMLINED)**

7524  
Diabetes mellitus type 2  
Treatment Phase: Initial treatment  
Clinical criteria:  
- The treatment must be in combination with metformin, **AND**  
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a dipeptidyl peptidase 4 inhibitor (gliptin) or a sodium-glucose co-transporter 2 (SGLT2) inhibitor; **OR**  
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.  

The date and level of the qualifying HbA1c measurement must be documented in the patient’s medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.  
The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient’s medical records.

ertugliflozin 15 mg + sitagliptin 100 mg tablet, 28

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**ERTUGLIFLOZIN + SITAGLIPTIN**

**Note** This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 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.

**Authority required (STREAMLINED)**

7556  
Diabetes mellitus type 2  
Treatment Phase: Continuing treatment  
Clinical criteria:  
- The treatment must be in combination with metformin, **AND**  
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.
### LINAGLIPTIN + METFORMIN

**Note** This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (gliptone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

**Note** PBS-subsidised dual oral therapy does not include combination use of a gliptin with an SGLT2 inhibitor; or
- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

### Authority required (STREAMLINED)

**7507**

**Diabetes mellitus type 2**

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and an SGLT2 inhibitor for this condition; **OR**
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

### linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60

**11274J**

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### linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60

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### LINAGLIPTIN + METFORMIN

**Note** Continuing Therapy Only:

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

### Authority required (STREAMLINED)

**6333**

**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 documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (gliptone), 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.

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

**Authority required (STREAMLINED)**

6326

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 is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

6344

Diabetes mellitus type 2

**Clinical criteria:**

- 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 optimal doses of dual oral therapy; 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 optimal doses of dual oral therapy.
- 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 optimal doses of dual oral therapy.
- 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 optimal doses of dual oral therapy.
- 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 optimal doses of dual oral therapy.
- 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 optimal doses of dual oral therapy.
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- 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 optimal doses of dual oral therapy.
- 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 optimal doses of dual oral therapy.
- 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 optimal doses of dual oral therapy.
- 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 optimal doses of dual oral therapy.

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 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
(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 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
(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 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
(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 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
(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 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
(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 glu
General Pharmaceutical Benefits

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, AND
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

Note: This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

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

linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60

linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60

linagliptin 2.5 mg + metformin hydrochloride 1 g 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

metformin hydrochloride 500 mg + glibenclamide 5 mg tablet, 90

SAXAGLIPTIN + DAPAGLIFLOZIN

Note: This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 inhibitor.

Authority required (STREAMLINED)

7524

Diabetes mellitus type 2

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with metformin, AND
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a dipeptidyl peptidase 4 inhibitor (gliptin) or a sodium-glucose co-transporter 2 (SGLT2) inhibitor; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.
### SAGGLIPTIN + DAPAGLIFLOZIN

#### Note
This fixed dose combination is not PBS-subsidised for use as a sole therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, an insulin, another dipeptidyl peptidase 4 inhibitor (gliptin), or another SGLT2 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.

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### SAXAGLIPTIN + METFORMIN

#### Note
This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

#### Note
PBS-subsidised dual oral therapy does not include combination use of:
- a gliptin with an SGLT2 inhibitor; or
- an SGLT2 inhibitor with a glitazone.

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### SAGGLIPTIN + METFORMIN

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patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**6333**

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.

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

**Authority required (STREAMLINED)**

**6335**

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 is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

**6344**

Diabetes mellitus type 2

**Clinical criteria:**
- 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 optimal doses of dual oral therapy; 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 optimal doses of dual oral therapy.

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.

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 fixed dose combination.

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

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.
Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or
• a gliptin with a glitazone; or
• an SGLT2 inhibitor with a glitazone.

### SITAGLIPTIN + METFORMIN

Note This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

Note PBS-subsidised dual oral therapy does not include combination use of: a gliptin with an SGLT2 inhibitor; or
• a gliptin with a glitazone; or
• an SGLT2 inhibitor with a glitazone.

### Authority required (STREAMLINED)

7507

Diabetes mellitus type 2

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and an SGLT2 inhibitor for this condition; **OR**
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

### sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56

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### General

- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.
- **SITAGLIPTIN + METFORMIN**

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

  **Authority required (STREAMLINED)**  
  6333 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.

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

  **Authority required (STREAMLINED)**  
  6334 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 is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

  **Authority required (STREAMLINED)**  
  6344 Diabetes mellitus type 2  
  **Clinical criteria:**  
  - 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 optimal doses of dual oral therapy; 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 optimal doses of dual oral therapy.  
  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.  
  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 fixed dose combination.

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

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

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 is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone) or a glucagon-like peptide-1.

### Authority required (STREAMLINED)

**7530**

Diabetes mellitus type 2

**Clinical criteria:**
• The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, AND
• Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

**Note**
This fixed dose combination is not PBS-subsidised for initiating dual oral combination treatment or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 analogue, or another dipeptidyl peptidase 4 inhibitor (gliptin).

**Note**
PBS-subsidised dual oral therapy does not include combination use of a gliptin with an SGLT2 inhibitor; or
• a gliptin with a glitazone; or
• an SGLT2 inhibitor with a glitazone.

### ALIMENTARY TRACT AND METABOLISM

### VILDAGLIPTIN + METFORMIN

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

### Authority required (STREAMLINED)

**6333**

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 of initiation 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 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.

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)**

**6357**

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.

**Authority required (STREAMLINED)**

**6344**

Diabetes mellitus type 2

**Clinical criteria:**

- 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 optimal doses of dual oral therapy; **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 optimal doses of dual oral therapy.

The date and level of the qualifying HbA1c measurement must be, or 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.

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 fixed dose combination.

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

**Authority required (STREAMLINED)**

**6443**

Diabetes mellitus type 2

**Clinical criteria:**

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

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

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

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

#### ACARBOSE

*acarbose 100 mg tablet, 90*

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*acarbose 50 mg tablet, 90*

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#### PIOLGLITAZONE

*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.

### Authority required (STREAMLINED)

#### 4363

Diabetes mellitus type 2

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

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

The HbA1c must be no more than 4 months old at the time 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 despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

#### 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.
**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.

**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; 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 despite treatment with either metformin or a sulfonylurea.

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

### 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.

**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.

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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.

### LINAGLIPTIN

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

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

#### Authority required (STREAMLINED)

**7541**
Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and an SGLT2 inhibitor; **OR**
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient’s medical records at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a glitazone.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a glitazone is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient’s medical records.

### Authority required (STREAMLINED)

**6346**
Diabetes mellitus type 2

**Clinical criteria:**

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

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

**Authority required (STREAMLINED)**

*6363* 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 optimal doses of dual oral therapy; 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 optimal doses of dual oral therapy.
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 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.

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

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

**Authority required (STREAMLINED)**

*6376* Diabetes mellitus type 2

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

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### Authority required (STREAMLINED)

**7505**

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

**Clinical criteria:**
- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

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

### LINAGLIPTIN

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

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

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### Authority required (STREAMLINED)

**7541**

Diabetes mellitus type 2

Treatment Phase: Initial treatment

**Clinical criteria:**
- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and an SGLT2 inhibitor; **OR**
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient’s medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient’s medical records.

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### SAXAGLIPTIN

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

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

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**SAXAGLIPTIN**

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

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

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

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

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

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

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 optimal doses of dual oral therapy; 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 was initiated.

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.

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

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

Clinical criteria:
- The treatment must be in combination with metformin, AND
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, AND
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

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

Note
PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.
saxagliptin 2.5 mg tablet, 28
10128C
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 57.31 41.00 Onglyza [AP]

saxagliptin 5 mg tablet, 28
8983T
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 57.31 41.00 Onglyza [AP]

**SITAGLIPTIN**

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

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

**Authority required (STREAMLINED)**
7541
Diabetes mellitus type 2

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and an SGLT2 inhibitor; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

**sitagliptin 100 mg tablet, 28**
11576G
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 52.78 41.00 Januvia [MK]

**sitagliptin 25 mg tablet, 28**
11572C
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 52.78 41.00 Januvia [MK]

**sitagliptin 50 mg tablet, 28**
11573D
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 52.78 41.00 Januvia [MK]

**SITAGLIPTIN**

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

**Authority required (STREAMLINED)**
6346
Diabetes mellitus type 2

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

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

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

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

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

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

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

### Authority required (STREAMLINED)

#### 6363

**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 optimal doses of dual oral therapy; **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 was initiated.

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

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

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

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

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

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

### Authority required (STREAMLINED)

#### 6376

**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 was initiated.

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

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 thiazolidinedione (glitazone), or a glucagon-like peptide-1.
**Authority required (STREAMLINED)**

**7505**

Diabetes mellitus type 2

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

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

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

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**sitagliptin 100 mg tablet, 28**

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**sitagliptin 25 mg tablet, 28**

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**VILDAGLIPTIN**

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

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**Authority required (STREAMLINED)**

**6346**

Diabetes mellitus type 2

**Clinical criteria:**

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

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

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

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

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

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

**Authority required (STREAMLINED)**

**6363**

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 optimal doses of dual oral therapy; **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 optimal doses of dual oral therapy. 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.

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

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

Authority required (STREAMLINED)

6376 Diabetes mellitus type 2

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

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

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

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

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

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

DULAGLUTIDE

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 SGLT2 inhibitor, an insulin or a sulfonylurea as dual therapy.

Note Special Pricing Arrangements apply.
(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)**

**5478**

Diabetes mellitus type 2

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

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

The HbA1c must be no more than 4 months old at the time 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.

**EXENATIDE**

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**56519**

Diabetes mellitus type 2

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

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

The HbA1c must be no more than 4 months old at the time 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.
• Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

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

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

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

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

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

**EXENATIDE**

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

### Authority required (STREAMLINED)

| 5500 |
| Diabetes mellitus type 2 |

**Clinical criteria:**

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

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

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

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

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

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

### Authority required (STREAMLINED)

| 5478 |
| 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 or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

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

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

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

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

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.
5469
Diabetes mellitus type 2
Clinical criteria:
- The treatment must be in combination with insulin, AND
- The treatment must be in combination with metformin unless contraindicated or not tolerated, AND
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptide 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

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

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

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

### SEMAGLUTIDE

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

**Note** Special Pricing Arrangements apply.

### Authority required (STREAMLINED)

**5500**
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 not tolerated a combination of metformin and a sulfonylurea; OR
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptide 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR
- Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

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

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

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

### Authority required (STREAMLINED)

**5478**
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
General Pharmaceutical Benefits

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

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

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

### Semaglutide 1.34 mg/mL injection, 1 x 3 mL pen device

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

#### Dapagliflozin

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

**Note** PBS-subsidised dual oral therapy does not include combination use of a gliptin with an SGLT2 inhibitor; or
- a gliptin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

### Authority required (STREAMLINED)

#### 7528

Diabetes mellitus type 2

**Clinical criteria:**
- The treatment must be in combination with metformin. **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a gliptin; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin. The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated. The HbA1c must be no more than 4 months old at the time of initiation of treatment with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient's medical records.

### Dapagliflozin 10 mg tablet, 28

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### Authority required (STREAMLINED)

#### 7506

Diabetes mellitus type 2

**Clinical criteria:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
• The 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 peptide 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

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

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with a gliptin and an SGLT2 inhibitor, must be documented in the patient’s medical records.

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

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

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**Authority required (STREAMLINED)**

4991
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 peptide 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.

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 thiazolidinedione (glitazone), or a glucagon-like peptide-1.

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**Authority required (STREAMLINED)**

5629
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 peptide 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; 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 optimal doses of dual oral therapy.

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

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

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

**Authority required (STREAMLINED)**

7495
Diabetes mellitus type 2

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a glitin for this condition.

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

Note: PBS subsidised dual oral therapy does not include combination use of:
- a glitin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**Empagliflozin 10 mg tablet, 28**

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- **EMPAGLIFLOZIN**

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

Note: PBS subsidised dual oral therapy does not include combination use of:
- a glitin with an SGLT2 inhibitor; or
- a glitin with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

**Authority required (STREAMLINED)**

7528
Diabetes mellitus type 2

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a gliptin; **OR**
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a glitin.

The date and level of the qualifying HbA1c measurement must be documented in the patient’s medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a glitin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a glitin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a glitin, must be documented in the patient’s medical records.

**Empagliflozin 10 mg tablet, 30**

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- **EMPAGLIFLOZIN**

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

**7506**

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 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 triple oral therapy with a gliptin and an SGLT2 inhibitor, must be documented in the patient’s medical records.

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

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

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**Authority required (STREAMLINED)**

**4991**

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.

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

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**Authority required (STREAMLINED)**

**5629**

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 optimal doses of dual oral therapy; 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 optimal doses of dual oral therapy.

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:
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- Had red cell transfusion within the previous 3 months.
The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

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

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

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

**Authority required** (STREAMLINED)

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**Diabetes mellitus type 2**

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

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

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

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**ERTUGLIFLOZIN**

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

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

---

**Authority required** (STREAMLINED)

---

**Diabetes mellitus type 2**

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and a gliptin; OR
- Patient must have, 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 of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is 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 triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin, must be documented in the patient’s medical records.

**ertugliflozin 5 mg tablet, 28**

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ERTUGLIFLOZIN

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

Authority required (STREAMLINED)
7506
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 triple oral therapy with a gliptin and an SGLT2 inhibitor, must be documented in the patient’s medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

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

Authority required (STREAMLINED)
7495
Diabetes mellitus type 2
Treatment Phase: Continuing treatment
Clinical criteria:
- The treatment must be in combination with metformin, AND
- The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), AND
- Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition.

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

Note
PBS-subsidised dual oral therapy does not include combination use of:
- a gliptin with an SGLT2 inhibitor; or
- a glitazone and a gliptin; or
- an SGLT2 inhibitor with a glitazone.
- The condition must be due to renal disease.

**Authority required (STREAMLINED)**

5255  
Hypoparathyroidism

**Authority required (STREAMLINED)**

5089  
Hypophosphataemic rickets

**Authority required (STREAMLINED)**

5114  
Vitamin D-resistant rickets

**Authority required (STREAMLINED)**

5402  
Established osteoporosis

**Clinical criteria:**
- Patient must have fracture due to minimal trauma.
- 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.

calcitriol 0.25 microgram capsule, 100

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

**Vitamin B1, plain**

**THIAMINE**

**Authority required (STREAMLINED)**

5139  
Thiamine deficiency

**Clinical criteria:**
- The treatment must be for prophylaxis.

**Population criteria:**
- Patient must be 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 carbonate 1.5 g (calcium 600 mg) tablet, 240

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calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120

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**POTASSEIUM**

**Potassium**
### ALIMENTARY TRACT AND METABOLISM

#### POTASSIUM CHLORIDE

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

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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) effervescent tablet, 60

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#### OTHER MINERAL SUPPLEMENTS

**Magnesium**

#### MAGNESIUM

**Authority required** (STREAMLINED)

5506
Hypomagnesaemia

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

**Authority required** (STREAMLINED)

5466
Chronic renal disease

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

MAGNESIUM 37.4 mg tablet, 50

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#### OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

**Amino acids and derivatives**

#### BETAINES

**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.

BETAINES 1 g/g powder for oral liquid, 180 g

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#### SAPROPTERIN

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Hyperphenylalaninaemia (HPA) due to tetrahydrobipterin (BH4) deficiency

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
- Must be treated by a metabolic physician; **OR**
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

**Clinical criteria:**
- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobipterin (BH4) deficiency, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

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

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Hyperphenylalaninaemia

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
- Must be treated by a metabolic physician; OR
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

**Clinical criteria:**
- Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.
- Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

**Note** Patient will be eligible for a maximum of one PBS-subsidised prescription as initial therapy to enable their response to treatment with sapropterin to be assessed.

### SAPROPTERIN

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Hyperphenylalaninaemia

**Treatment Phase:** Initial treatment

**Treatment criteria:**
- Must be treated by a metabolic physician.

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

**Note** Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Patient will be eligible for a maximum of one PBS-subsidised prescription as initial therapy to enable their response to treatment with sapropterin to be assessed.

**Authority required**

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

**Treatment Phase: Initial treatment - responsiveness testing**

**Treatment criteria:**
- Must be treated by a metabolic physician.

**Clinical criteria:**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a baseline blood phenylalanine level above 360 micromole per L and be less than one month of age; **OR**
- Patient must have a baseline blood phenylalanine level above 600 micromole per L and be more than one month of age, **AND**
- The treatment must be for the purpose of initial responsiveness testing for a period of 24 hours in a patient less than one month of age; **OR**
- The treatment must be for the purpose of initial responsiveness testing for a period of 7 days in a patient aged more than one month.

**Population criteria:**
- Patient must be under 18 years of age.
Dietary phenylalanine intake must be maintained at a constant level. Patients or their parent/guardian should be assessed for their ability to comply with the sapropterin protocol and PKU diet prior to conducting initial responsiveness testing.

**sapropterin dihydrochloride 100 mg soluble tablet, 30**

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**sapropterin dihydrochloride 500 mg powder for oral liquid, 30 sachets**

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**SAPROPTERIN**

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

**Treatment Phase: First continuing treatment**

**Treatment criteria:**
- Must be treated by a metabolic physician; **OR**
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment under the Initial treatment - responsiveness testing restriction with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug of greater than or equal to a 30% reduction in phenylalanine levels from baseline during initial responsiveness testing.

**Population criteria:**
- Patient must have been under 18 years of age at the time treatment with this drug was initiated for this condition.
Blood phenylalanine levels must be based on measurements taken during stable periods of the condition.
Dietary phenylalanine intake must be maintained at a constant level.

**Authority required**

Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)

**Treatment Phase: Subsequent continuing**

**Treatment criteria:**
- Must be treated by a metabolic physician; **OR**
- Must be treated by a nurse practitioner experienced in the treatment of phenylketonuria in consultation with a metabolic physician.

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must be undergoing regular phenylalanine testing and assessment of adherence to dietary modifications.

**Population criteria:**
- Patient must have been under 18 years of age at the time treatment with this drug was initiated for this condition.
BLOOD AND BLOOD FORMING ORGANS

**SODIUM PHENYLButYRATE**

**Authority required (STREAMLINED)**

*9993*

Urea cycle disorders

**Clinical criteria:**

- Patient must have elevated ammonia levels that are not controlled with diet alone and other adjunct care alone.

An increase in the maximum quantity will be authorised to provide for up to one month’s supply at a dose of up to 600 mg/kg/day in patients weighing less than 20 kg and up to 13 g/m²/day in patients weighing more than 20 kg.

**Authority required (STREAMLINED)**

*9919*

Urea cycle disorders

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

An increase in the maximum quantity will be authorised to provide for up to one month’s supply at a dose of up to 600 mg/kg/day in patients weighing less than 20 kg and up to 13 g/m²/day in patients weighing more than 20 kg.

**Authority required (STREAMLINED)**

*9888*

Urea cycle disorders

**Clinical criteria:**

- Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2019.

An increase in the maximum quantity will be authorised to provide for up to one month’s supply at a dose of up to 600 mg/kg/day in patients weighing less than 20 kg and up to 13 g/m²/day in patients weighing more than 20 kg.

**BLOOD AND BLOOD FORMING ORGANS**

**ANTITHROMBOTIC AGENTS**

**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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Heparin group

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General Pharmaceutical Benefits 105
### DALTEPARIN SODIUM

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

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

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

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### DALTEPARIN SODIUM

#### Restricted benefit

#### Haemodialysis

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

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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>2</td>
<td>3</td>
<td>..</td>
<td>*138.16</td>
<td>41.00</td>
<td>Fragmin [PF]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*191.98</td>
<td>41.00</td>
<td>Fragmin [PF]</td>
</tr>
</tbody>
</table>

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

<table>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
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<td>..</td>
<td>*84.62</td>
<td>41.00</td>
<td>Fragmin [PF]</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*87.64</td>
<td>41.00</td>
<td>Fragmin [PF]</td>
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</tbody>
</table>

#### dalteparin sodium 7500 anti-Xa units/0.75 mL injection, 10 x 0.75 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>2</td>
<td>3</td>
<td>..</td>
<td>*103.52</td>
<td>41.00</td>
<td>Fragmin [PF]</td>
</tr>
</tbody>
</table>

### DALTEPARIN SODIUM

#### Note

No applications for increased maximum quantities will be authorised.

**Restricted benefit**

Symptomatic venous thromboembolism

**Clinical criteria:**

- Patient must have a solid tumour(s).

#### dalteparin sodium 10 000 anti-Xa 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>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>3</td>
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<td>..</td>
<td>*203.73</td>
<td>41.00</td>
<td>Fragmin [PF]</td>
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</tbody>
</table>

#### dalteparin sodium 12 500 anti-Xa units/0.5 mL injection, 10 x 0.5 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>3</td>
<td>5</td>
<td>..</td>
<td>*284.46</td>
<td>41.00</td>
<td>Fragmin [PF]</td>
</tr>
</tbody>
</table>

#### dalteparin sodium 15 000 anti-Xa units/0.6 mL injection, 10 x 0.6 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>3</td>
<td>5</td>
<td>..</td>
<td>*339.90</td>
<td>41.00</td>
<td>Fragmin [PF]</td>
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</table>
### Enoxaparin Sodium

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand Name and Manufacturer</th>
<th>Dose</th>
<th>Product Description</th>
<th>Injections</th>
<th>Syringes</th>
<th>Ampoules</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>8558K</td>
<td>Clexane [SW], Enoxaparin Winthrop [WA]</td>
<td>20 mg/0.2 mL</td>
<td>Injection, 10 x 0.2 mL syringes</td>
<td>10</td>
<td>0.2 mL</td>
<td>50 x 5 mL ampoules</td>
<td>3</td>
</tr>
<tr>
<td>8510X</td>
<td>Clexane [SW], Enoxaparin Winthrop [WA]</td>
<td>40 mg/0.4 mL</td>
<td>Injection, 10 x 0.4 mL syringes</td>
<td>10</td>
<td>0.4 mL</td>
<td>100 x 0.6 mL syringes</td>
<td>2</td>
</tr>
<tr>
<td>8264Y</td>
<td>Clexane [SW], Enoxaparin Winthrop [WA]</td>
<td>100 mg/mL</td>
<td>Injection, 10 x 1 mL syringes</td>
<td>10</td>
<td>1 mL</td>
<td>25 x 1 mL ampoules</td>
<td>1</td>
</tr>
<tr>
<td>8262W</td>
<td>Clexane [SW], Enoxaparin Winthrop [WA]</td>
<td>60 mg/0.6 mL</td>
<td>Injection, 10 x 0.6 mL syringes</td>
<td>10</td>
<td>0.6 mL</td>
<td>100 x 0.72 mL syringes</td>
<td>1</td>
</tr>
<tr>
<td>8263X</td>
<td>Clexane [SW], Enoxaparin Winthrop [WA]</td>
<td>80 mg/0.8 mL</td>
<td>Injection, 10 x 0.8 mL syringes</td>
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<td>0.8 mL</td>
<td>100 x 0.75 mL syringes</td>
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</table>

### Heparin

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand Name and Manufacturer</th>
<th>Dose</th>
<th>Product Description</th>
<th>Injections</th>
<th>Syringes</th>
<th>Ampoules</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>1463B</td>
<td>Pfizer Australia Pty Ltd [PF]</td>
<td>5000 units/5 mL</td>
<td>Injection, 50 x 5 mL ampoules</td>
<td>1</td>
<td>5</td>
<td>73.24</td>
<td>41.00</td>
</tr>
<tr>
<td>1466E</td>
<td>DBL Heparin Sodium [PF]</td>
<td>5000 units/0.2 mL</td>
<td>Injection, 5 x 0.2 mL ampoules</td>
<td>1</td>
<td>5</td>
<td>24.34</td>
<td>25.63</td>
</tr>
</tbody>
</table>
### NADROPARIN

**nadroparin calcium 2850 anti-Xa units/0.3 mL injection, 2 x 0.3 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>10</td>
<td>..</td>
<td>..</td>
<td>65.74</td>
<td>41.00</td>
<td>Fraxiparine [AS]</td>
</tr>
</tbody>
</table>

**nadroparin calcium 3800 anti-Xa units/0.4 mL injection, 2 x 0.4 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>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>..</td>
<td>..</td>
<td>83.54</td>
<td>41.00</td>
<td>Fraxiparine [AS]</td>
</tr>
</tbody>
</table>

**nadroparin calcium 5700 anti-Xa units/0.6 mL injection, 2 x 0.6 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>10</td>
<td>..</td>
<td>..</td>
<td>119.64</td>
<td>41.00</td>
<td>Fraxiparine [AS]</td>
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</tbody>
</table>

**nadroparin calcium 15 200 anti-Xa units/0.8 mL injection, 2 x 0.8 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>5</td>
<td>1</td>
<td>157.19</td>
<td>41.00</td>
<td></td>
<td>Fraxiparine Forte [AS]</td>
</tr>
</tbody>
</table>

**nadroparin calcium 19 000 anti-Xa units/mL injection, 2 x 1 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>5</td>
<td>1</td>
<td>194.69</td>
<td>41.00</td>
<td></td>
<td>Fraxiparine Forte [AS]</td>
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</tbody>
</table>

**nadroparin calcium 7600 anti-Xa units/0.8 mL injection, 2 x 0.8 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>5</td>
<td>..</td>
<td>83.54</td>
<td>41.00</td>
<td></td>
<td>Fraxiparine [AS]</td>
</tr>
</tbody>
</table>

**nadroparin calcium 9500 anti-Xa units/mL injection, 2 x 1 mL syringes**

<table>
<thead>
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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>5</td>
<td>..</td>
<td>101.44</td>
<td>41.00</td>
<td></td>
<td>Fraxiparine [AS]</td>
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</tbody>
</table>

**nadroparin calcium 11 400 anti-Xa units/0.6 mL injection, 2 x 0.6 mL syringes**

<table>
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<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>119.64</td>
<td>41.00</td>
<td></td>
<td>Fraxiparine Forte [AS]</td>
</tr>
</tbody>
</table>

### NADROPARIN

**Restricted benefit**

Hemodialysis

**nadroparin calcium 2850 anti-Xa units/0.3 mL injection, 2 x 0.3 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>10</td>
<td>3</td>
<td>*65.74</td>
<td>41.00</td>
<td></td>
<td>Fraxiparine [AS]</td>
</tr>
</tbody>
</table>

**nadroparin calcium 3800 anti-Xa units/0.4 mL injection, 2 x 0.4 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>10</td>
<td>3</td>
<td>*83.54</td>
<td>41.00</td>
<td></td>
<td>Fraxiparine [AS]</td>
</tr>
</tbody>
</table>

**nadroparin calcium 5700 anti-Xa units/0.6 mL injection, 2 x 0.6 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>10</td>
<td>3</td>
<td>*119.64</td>
<td>41.00</td>
<td></td>
<td>Fraxiparine [AS]</td>
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</tbody>
</table>

**nadroparin calcium 1900 anti-Xa units/0.2 mL injection, 2 x 0.2 mL syringes**

<table>
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</tr>
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<tbody>
<tr>
<td>10</td>
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<td>*47.84</td>
<td>41.00</td>
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<td>Fraxiparine [AS]</td>
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</table>

**nadroparin calcium 7600 anti-Xa units/0.8 mL injection, 2 x 0.8 mL syringes**

<table>
<thead>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>10</td>
<td>3</td>
<td>*119.64</td>
<td>41.00</td>
<td></td>
<td>Fraxiparine Forte [AS]</td>
</tr>
</tbody>
</table>

**Platelet aggregation inhibitors excl. heparin**
BLOOD AND BLOOD FORMING ORGANS

### ASPIRIN

**Restricted benefit**

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

#### aspirin 100 mg tablet, 112

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>8202Q</td>
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<td>..</td>
<td>13.86</td>
<td>15.15</td>
<td>Spren 100 [OW]</td>
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</tbody>
</table>

### CLOPIDOGREL

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

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

**Note** Shared Care Model:

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

#### 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.

#### clopidogrel 75 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>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>2275R</td>
<td>1</td>
<td>5</td>
<td>16.11</td>
<td>17.40</td>
<td>* BTC Clopidogrel [JB]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Clopidogrel-GA [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Clopidogrel 75 [RW]</td>
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</table>

#### clopidogrel 75 mg tablet, 28

<table>
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<th>Max Qty Packs</th>
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<td>9317J</td>
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<td>17.40</td>
<td>* APO-Clopidogrel [TX]</td>
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<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>* Clopidogrel Sandoz Pharma [HK]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Iscover [AV]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Blooms the Chemist Clopidogrel [IB]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Clopidogrel Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Clopidogrel Winthrop [WA]</td>
</tr>
</tbody>
</table>

### CLOPIDOGREL

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

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

**Note** Shared Care Model:

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

#### Authority required (STREAMLINED)

**5517**

Prevention of recurrence of myocardial infarction or unstable angina

**Clinical criteria:**

- Patient must have a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin.

#### Authority required (STREAMLINED)

**5524**

Prevention of recurrence of myocardial infarction or unstable angina

**Clinical criteria:**

- Patient must be in one whom low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

#### Authority required (STREAMLINED)

**5525**

Prevention of recurrence of myocardial infarction or unstable angina

**Clinical criteria:**

- Patient must have a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs (NSAIDs).
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**
- Patient must have a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin.

**Authority required (STREAMLINED)**

**5436**
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**
- Patient must be in one whom low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

**Authority required (STREAMLINED)**

**5508**
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

**Clinical criteria:**
- Patient must have a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs (NSAIDs).

---

### CLOPIDOGREL + ASPIRIN

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

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

**Authority required (STREAMLINED)**

**5488**
Acute coronary syndrome (myocardial infarction or unstable angina)

**Authority required (STREAMLINED)**

**5443**
Cardiac stent insertion

**Clinical criteria:**
- The treatment must follow insertion of a cardiac stent.

**Authority required (STREAMLINED)**

**5517**
Prevention of recurrence of myocardial infarction or unstable angina

**Clinical criteria:**
- Patient must have a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin.

---

### DIPYRIDAMOLE + 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.

**Restricted benefit**
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events
dipyridamole 200 mg + aspirin 25 mg modified release capsule, 60
8382E

<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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**EPTIFIBATIDE**

**Authority required (STREAMLINED)**

6435

Coronary artery disease

**Treatment criteria:**
- Patient must be undergoing non-urgent percutaneous intervention with intracoronary stenting.

**Eptifibatide 75 mg/100 mL injection, 100 mL vial**

8684C

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**Eptifibatide 20 mg/10 mL injection, 10 mL vial**

8683B

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**TICAGRELOR**

**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.

**Authority required (STREAMLINED)**

5746

Acute coronary syndrome (myocardial infarction or unstable angina)

**Clinical criteria:**
- The treatment must be in combination with aspirin.

**Ticagrelor 90 mg tablet, 56**

1418P

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**TIROFIBAN**

**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.

**Authority required (STREAMLINED)**

5782

High risk of unstable angina

**Clinical criteria:**
- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have pain lasting longer than 20 minutes.

**Authority required (STREAMLINED)**

5809

High risk of unstable angina

**Clinical criteria:**
- Patient must have new transient or persistent ST-T ischaemic changes, **AND**
- Patient must have repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours.

**Authority required (STREAMLINED)**

5691

Non-Q-wave myocardial infarction

**Tirofiban 12.5 mg/50 mL injection, 50 mL vial**

8350L

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**Enzymes**

**RETEPLASE**

**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.

**Restricted benefit**

Acute myocardial infarction
Clinical criteria:
- The treatment must be administered within 6 hours of the onset of attack.

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**TENECTEPLASE**

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.

Clinical criteria:
- The treatment must be administered within 12 hours of onset of attack.

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**Direct thrombin inhibitors**

**BIVALIRUDIN**

Authority required (STREAMLINED)

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**DABIGATRAN**

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

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

Authority required (STREAMLINED)

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</table>
Prevention of venous thromboembolism

Treatment criteria:
- Patient must be undergoing total hip replacement.

Clinical criteria:
- Patient must require up to 20 days supply to complete a course of treatment.

dabigatran etexilate 75 mg capsule, 10

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Prevention of venous thromboembolism

Treatment criteria:
- Patient must be undergoing total knee replacement.

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

dabigatran etexilate 75 mg capsule, 10

<table>
<thead>
<tr>
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Prevention of stroke or systemic embolism

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

dabigatran etexilate 110 mg capsule, 10

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dabigatran etexilate 150 mg capsule, 10

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APIXABAN

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

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

Authority required (STREAMLINED)
4402
Prevention of venous thromboembolism

Treatment criteria:
• Patient must be undergoing total hip replacement.

Clinical criteria:
• Patient must require up to 30 days supply to complete a course of treatment.

apixaban 2.5 mg tablet, 60

<table>
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APIXABAN

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

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

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)
5098
Pulmonary embolism

Treatment Phase: Initial treatment

Clinical criteria:
• Patient must have confirmed acute symptomatic pulmonary embolism.

apixaban 5 mg tablet, 28

<table>
<thead>
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APIXABAN

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

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

Authority required (STREAMLINED)
4382
Prevention of venous thromboembolism

Treatment criteria:
• Patient must be undergoing total knee replacement.

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

Authority required (STREAMLINED)
4409
Prevention of venous thromboembolism

Treatment criteria:
• Patient must be undergoing total hip replacement.

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

#### 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.

#### Authority required (STREAMLINED)

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<td>Patient must be undergoing total knee replacement.</td>
</tr>
<tr>
<td>4359</td>
<td>Prevention of venous thromboembolism</td>
<td>Patient must be undergoing total hip replacement.</td>
</tr>
</tbody>
</table>

#### 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:
1. Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
2. Age 75 years or older;
3. Hypertension;
4. Diabetes mellitus;
5. Heart failure and/or left ventricular ejection fraction 35% or less.

#### Authority required (STREAMLINED)

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#### APIXABAN

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<td>Prevention of stroke or systemic embolism</td>
<td>Patient must have non-valvular atrial fibrillation, AND</td>
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#### Clinical criteria:
- Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:
1. Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
2. Age 75 years or older;
3. Hypertension;
4. Diabetes mellitus;
5. Heart failure and/or left ventricular ejection fraction 35% or less.

#### Authority required (STREAMLINED)

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### APIXABAN

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<tr>
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<tbody>
<tr>
<td>4359</td>
<td>Prevention of venous thromboembolism</td>
<td>Patient must be undergoing total hip replacement.</td>
</tr>
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</table>

#### Clinical criteria:
- Patient must require up to 10 days supply to complete a course of treatment.

#### Authority required (STREAMLINED)

<table>
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<th>Code</th>
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<th>Clinical criteria</th>
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<td>Patient must be undergoing total hip replacement.</td>
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</table>

#### Clinical criteria:
- Patient must require up to 10 days supply to complete a course of treatment.

#### Authority required (STREAMLINED)

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<td>Patient must have a history of venous thromboembolism.</td>
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Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

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 Special Pricing Arrangements apply.

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)

5083
Pulmonary embolism
Treatment Phase: Continuing treatment
Clinical criteria:
• Patient must have confirmed acute symptomatic pulmonary embolism.

apixaban 5 mg tablet, 60

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RIVAROXABAN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

11013
Chronic stable atherosclerotic disease
Treatment Phase: Initial treatment
Clinical criteria:
• The treatment must be in combination with aspirin, but not with any other anti-platelet therapy, AND
• Patient must have a diagnosis of coronary artery disease in addition to at least one of the following risk factors: (i) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (ii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iii) diabetes mellitus combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent; OR
• Patient must have a diagnosis of peripheral artery disease in addition to at least one of the following risk factors: (i) concomitant coronary artery disease (ii) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (iii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iv) diabetes mellitus combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent, AND
• Patient must have at least one of the following if coronary artery disease is present: (i) a previous multi-vessel coronary revascularisation procedure (ii) significant stenosis in at least 2 coronary arteries (iii) a previous single vessel coronary revascularisation procedure with significant stenosis in more than 1 coronary artery; OR
• Patient must have at least one of the following if peripheral arterial disease is present: (i) a previous peripheral/carotid artery revascularisation intervention (ii) intermittent claudication with an ankle-brachial index less than 0.9 (iii) asymptomatic carotid artery stenosis greater than 50%, AND
• The condition must be diagnosed by at least one of: (i) invasive (selective) angiography (ii) non-invasive imaging (i.e. CT scan, ultrasound) (iii) ankle-brachial index measurement in the case of peripheral arterial disease with intermittent claudication, AND
• Patient must have clinical findings/observations by the treating physician that exclude each of the following: (i) high risk of bleeding (ii) prior stroke within one month of treatment initiation (iii) prior haemorrhagic / lacunar stroke (iv) severe heart failure with a known ejection fraction less than 30% (v) New York Heart Association class III to IV heart failure symptoms (i.e. symptoms corresponding to moderate to severe limitation on physical activity, whereby any of fatigue/palpitations/dyspnoea occur upon zero to minimal activity) (vi) an estimated glomerular filtration rate less than 15
mL/minute (vii) a requirement for dual antiplatelet therapy (viii) a requirement for non-acetylsalicylic acid antiplatelet therapy (ix) a requirement for a higher dose of oral anticoagulant therapy.

**Treatment criteria:**
- Must be treated by a specialist physician; OR
- Must be treated by a physician who has consulted a specialist physician.

**rivaroxaban 2.5 mg tablet, 60**

<table>
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**RIVAROXABAN**

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

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

**Note Shared Care Model:**
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**Authority required (STREAMLINED)**
4369
Prevention of venous thromboembolism

**Treatment criteria:**
- Patient must be undergoing total hip replacement.

**Clinical criteria:**
- Patient must require up to 20 days supply to complete a course of treatment.

**rivaroxaban 10 mg tablet, 10**

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**RIVAROXABAN**

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

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

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

**Authority required (STREAMLINED)**
4402
Prevention of venous thromboembolism

**Treatment criteria:**
- Patient must be undergoing total hip replacement.

**Clinical criteria:**
- Patient must require up to 30 days supply to complete a course of treatment.

**rivaroxaban 10 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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<td>1</td>
<td></td>
<td>1</td>
<td>Xarelto [BN]</td>
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</table>

**RIVAROXABAN**

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

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

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

**Authority required (STREAMLINED)**
4381
Prevention of venous thromboembolism

**Treatment criteria:**
- Patient must be undergoing total knee replacement.

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

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

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

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

**Authority required (STREAMLINED)**

**4382**
Prevention of venous thromboembolism

**Treatment criteria:**
- Patient must be undergoing total knee replacement.

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

---

**RIVAROXABAN**

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

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

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

**Authority required (STREAMLINED)**

**4132**
Prevention of recurrent venous thromboembolism

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have a history of venous thromboembolism.

---

**RIVAROXABAN**

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

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

**Special Pricing Arrangements apply.**

**Authority required (STREAMLINED)**

**4382**
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.
RIVAROXABAN

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

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Treatment may be continued by a non-specialist prescriber without need for consultation with a specialist.

Authority required (STREAMLINED)
10992
Chronic stable atherosclerotic disease
Treatment Phase: Continuing treatment
Clinical criteria:
• Patient must have received PBS-subsidised treatment with this drug for this condition, AND
• The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.

Rivaroxaban 2.5 mg tablet, 60

12192Q
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 . 85.38 41.00 Xarelto [BN]

RIVAROXABAN

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

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

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.

Rivaroxaban 15 mg tablet, 42

2160Q
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 . . 114.86 41.00 Xarelto [BN]

RIVAROXABAN

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

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

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.

**Note**

Special Pricing Arrangements apply.

---

**Authority required (STREAMLINED)**

**4269**

Prevention of stroke or systemic embolism

**Clinical criteria:**

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

Risk factors for developing stroke or systemic ischaemic embolism are:

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

**Note**

Special Pricing Arrangements apply.

---

**rivaroxaban 20 mg tablet, 28**

**2268J**

**Max.Qty Packs**

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**Other antithrombotic agents**

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

**Authority required (STREAMLINED)**

**5781**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing major hip surgery.

**Authority required (STREAMLINED)**

**5808**

Prevention of venous thromboembolism

**Treatment criteria:**

- Patient must be undergoing total knee replacement.

**fondaparinux sodium 2.5 mg/0.5 mL injection, 2 x 0.5 mL syringes**

**8775W**

**Max.Qty Packs**

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---

**ANTIHEMORRHAGICS**

**ANTIFIBRINOLYTICS**

**Amino acids**

- **TRANEXAMIC ACID**

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

**tranexamic acid 500 mg tablet, 100**

**2180R**

**Max.Qty Packs**

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<td></td>
<td></td>
<td></td>
<td>* Cyklokapron [PF]</td>
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# ANTIANEMIC PREPARATIONS

## IRON PREPARATIONS

### Iron bivalent, oral preparations

#### FERROUS FUMARATE

**Restricted benefit**

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

**ferrous fumarate 200 mg (iron 65.7 mg) tablet, 60**

<table>
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#### FERROUS SULFATE

**ferrous sulfate heptahydrate 30 mg/mL (iron 6 mg/mL) oral liquid, 250 mL**

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## FERRIC CARBOXYMALTOSE

**Note** Special Pricing Arrangements apply.

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

<table>
<thead>
<tr>
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<td>*298.76</td>
<td>41.00</td>
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**iron (as ferric carboxymaltose) 1 g/20 mL injection, 20 mL vial**

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</table>

## FERRIC DERISOMALTOSE

**Note** Special Pricing Arrangements apply.

**iron (as ferric derisomaltose) 1 g/10 mL injection, 10 mL vial**

<table>
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<tr>
<th>Max Qty Packs</th>
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**iron (as ferric derisomaltose) 500 mg/5 mL injection, 5 mL vial**

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<td>*444.63</td>
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</table>

## IRON POLYMALTOSE

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

<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>31.26</td>
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<td>Ferrosig [SI]</td>
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</table>

## IRON POLYMALTOSE

**Authority required (STREAMLINED)**

4302  
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 Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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## IRON SUCROSE

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

<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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## IRON SUCROSE

**Authority required (STREAMLINED)**

4302  
Iron deficiency anaemia
General

BLOOD AND BLOOD FORMING ORGANS

Schedule of Pharmaceutical Benefits – December 2020

Treatment criteria:
- Patient must be undergoing chronic haemodialysis.

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

<table>
<thead>
<tr>
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Iron in combination with folic acid

**Ferrofumarate + Folic Acid**

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

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

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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**Vitamin B12 and Folic Acid**

Vitamin B12 (cyanocobalamin and analogues)

**Hydroxocobalamin**

*Note* One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B12 deficiencies.

*Note* Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

*Restricted benefit*
Pernicious anaemia

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

*Restricted benefit*
Proven vitamin B12 deficiencies other than pernicious anaemia

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

**Clinical criteria:**
- Patient must have had a gastrectomy, AND
- The treatment must be for prophylaxis.

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

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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**Hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules**

<table>
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**Folic Acid and Derivatives**

**Folic Acid**

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

**Folic acid 500 microgram tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>17.37</td>
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<td>Foltabs 500 [PP]</td>
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<td></td>
<td></td>
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<td>Megafol 0.5 [AF]</td>
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**Folic Acid 5 mg tablet, 100**

<table>
<thead>
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<th>DPMQ $</th>
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<td>*18.30</td>
<td>19.59</td>
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<td>Megafol 5 [AF]</td>
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</table>

**Note** The 5 mg strength tablet should be used in malabsorption states only.
CARDIOVASCULAR SYSTEM

BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

BLOOD AND RELATED PRODUCTS

Blood substitutes and plasma protein fractions

**HYDROXYETHYL STARCH 130/0.4 + SODIUM CHLORIDE**

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

<table>
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<td>*41.79</td>
<td>41.00</td>
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**OTHER HEMATOLOGICAL AGENTS**

**ICATIBANT**

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)

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.

Increased maximum quantities will be limited to 12 injections per authority prescription.

Authority required

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Continuing

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Increased maximum quantities will be limited to 12 injections per authority prescription.

Icatibant 30 mg/3 mL injection, 3 mL syringe

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**CARDIOVASCULAR SYSTEM**

**CARDIAC THERAPY**

**CARDIAC GLYCOSIDES**

Digitalis glycosides

**DIGOXIN**

Note: Shared Care Model:

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

Digoxin 50 microgram/mL oral liquid, 60 mL

<table>
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<td>2</td>
<td>3</td>
<td>..</td>
<td>*42.22</td>
<td>41.00</td>
<td></td>
<td>Lanoxin [AS]</td>
</tr>
</tbody>
</table>

Digoxin 250 microgram tablet, 100

<table>
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<tr>
<th>1322N</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>1</td>
<td>1</td>
<td>..</td>
<td>15.75</td>
<td>17.04</td>
<td></td>
<td>* Sigmaxin [LN]</td>
</tr>
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</table>

1.56  18.31  17.04  * Lanoxin [AS]
digoxin 62.5 microgram tablet, 200
260SD

<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>1</td>
<td>..</td>
<td>15.50</td>
<td>16.79</td>
<td>* Sigmaxin-PG [LN]</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>2.56</strong></td>
<td>18.06</td>
<td>16.79</td>
<td>* Lanoxin-PG [AS]</td>
</tr>
</tbody>
</table>

ANTIARRHYTHMICS, CLASS I AND III
Antiarhythmics, class Ia

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

- **LIDOCAINE (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.

- **FLECAINIDE**
  - **Caution** Flecainide acetate should be avoided in patients with poor cardiac function.
  - **Note Shared Care Model:**
    For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

- **AMIODARONE**
  - **Note** This drug has been reported to cause frequent and potentially serious toxicity.
  - **Note** Regular monitoring of hepatic and thyroid function is recommended.
  - **Note Shared Care Model:**
    For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
**General Pharmaceutical Benefits**

**CARDIOVASCULAR SYSTEM**

### General amiodarone hydrochloride 200 mg tablet, 30

<table>
<thead>
<tr>
<th>2343H</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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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>19.76</td>
<td>21.05</td>
<td>A</td>
<td>Amiodarone Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* APO-Amiodarone [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Aratac 200 [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Rithmik 200 [RW]</td>
</tr>
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</table>

**SOTALOL**

**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.

### Restricted benefit

Severe cardiac arrhythmias

### sotalol hydrochloride 160 mg tablet, 60

<table>
<thead>
<tr>
<th>2043M</th>
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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>
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<tbody>
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<td>18.93</td>
<td>20.22</td>
<td>A</td>
<td>APO-Sotalol [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Cardol [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Solavert [RF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Sotalol Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4.33</td>
<td>23.26</td>
<td></td>
<td>Sotacor [RW]</td>
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### sotalol hydrochloride 80 mg tablet, 60

<table>
<thead>
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<th>8398B</th>
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<th>DPMQ</th>
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<tbody>
<tr>
<td>1</td>
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<td>15.23</td>
<td>16.52</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Cardol [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Solavert [RF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Sotalol Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>4.33</td>
<td>19.56</td>
<td></td>
<td>Sotacor [RW]</td>
</tr>
</tbody>
</table>

**CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES**

**Adrenergic and dopaminergic agents**

### ADRENALINE (EPINEPHRINE)

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

<table>
<thead>
<tr>
<th>1016L</th>
<th>Max Qty</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>..</td>
<td>21.68</td>
<td>22.97</td>
<td>Link</td>
<td>Medical Products Pty Ltd</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>[LM]</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>5004J</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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>21.68</td>
<td>22.97</td>
<td>Link</td>
<td>Medical Products Pty Ltd</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>[LM]</td>
<td></td>
</tr>
</tbody>
</table>

### ADRENALINE (EPINEPHRINE)

**Note** The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

**Note** Authority approvals will be limited to a maximum quantity of 2 auto-injectors at any one time.

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

**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 (epinephrine) 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.
### CARDIOVASCULAR SYSTEM

#### VASODILATORS USED IN CARDIAC DISEASES

**Organic nitrates**

<table>
<thead>
<tr>
<th>Gluceryl trinitrate 10 mg/24 hours patch, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Gluceryl trinitrate 10 mg/24 hours patch, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Gluceryl trinitrate 5 mg/24 hours patch, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
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<tr>
<td>1</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Gluceryl trinitrate 5 mg/24 hours patch, 30</th>
</tr>
</thead>
<tbody>
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<td>Max Qty Packs</td>
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</table>

<table>
<thead>
<tr>
<th>Gluceryl trinitrate 15 mg/24 hours patch, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

**Note** The spray should not be inhaled.

<table>
<thead>
<tr>
<th>Gluceryl trinitrate 400 microgram/actuation spray, 200 actuations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>§1</td>
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</tbody>
</table>

**Isosorbide dinitrate**

<table>
<thead>
<tr>
<th>Isosorbide dinitrate 5 mg sublingual tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2</td>
</tr>
</tbody>
</table>

**Isosorbide mononitrate 60 mg modified release tablet, 30**

<table>
<thead>
<tr>
<th>Isosorbide mononitrate 60 mg modified release tablet, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
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<tr>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Isosorbide mononitrate 60 mg modified release tablet, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
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<tr>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Isosorbide mononitrate 120 mg modified release tablet, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

**Other vasodilators used in cardiac diseases**

**Nicorandil**

**Note** Shared Care Model:

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

### General Pharmaceutical Benefits

<table>
<thead>
<tr>
<th>nicorandil 10 mg tablet, 60</th>
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<tbody>
<tr>
<td>8228C</td>
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<table>
<thead>
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<tr>
<td>8229D</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>$1</td>
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</table>

### PERHEXILINE

**Note** Regular monitoring of drug serum levels is recommended.

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

<table>
<thead>
<tr>
<th>perhexiline maleate 100 mg tablet, 100</th>
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</thead>
<tbody>
<tr>
<td>1822X</td>
</tr>
<tr>
<td>Max Qty Packs</td>
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<td>1</td>
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</tbody>
</table>

### OTHER CARDIAC PREPARATIONS

**Other cardiac preparations**

### IVABRADINE

**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>ivabradine 5 mg tablet, 56</th>
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</thead>
<tbody>
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<td>Max Qty Packs</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>ivabradine 7.5 mg tablet, 56</th>
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<tbody>
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<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
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</tbody>
</table>

### ANTIHYPERTENSIVES

#### ANTIADRENERGIC AGENTS, CENTRALLY ACTING

**Methyldopa**

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<td>Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
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</table>

**Imidazoline receptor agonists**

---

General Pharmaceutical Benefits 127
### CLONIDINE

**clonidine hydrochloride 100 microgram tablet, 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>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>5</td>
<td>27.60</td>
<td>* APO-Clonidine [TX]</td>
<td>* Catapres 100 [BY]</td>
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**clonidine hydrochloride 150 microgram tablet, 100**

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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>
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<td>1</td>
<td>5</td>
<td>33.55</td>
<td>Catapres [BY]</td>
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</tbody>
</table>

### GUANFACINE

**Note** Special Pricing Arrangements apply.

---

**Authority required (STREAMLINED) 9034**

Attention deficit hyperactivity disorder

**Treatment Phase: Initial treatment**

**Treatment criteria:**
- Must be treated by a paediatrician or psychiatrist.

**Clinical criteria:**
- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; **OR**
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine 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 dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

**Population criteria:**
- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.

---

**Authority required (STREAMLINED) 9031**

Attention deficit hyperactivity disorder

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; **OR**
- Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine 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 dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

---

**Authority required (STREAMLINED) 8544**

Attention deficit hyperactivity disorder

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- Must be treated by a paediatrician or psychiatrist.

**Clinical criteria:**
- The condition must be or have been diagnosed according to the DSM-5 criteria, **AND**
- Patient must be receiving a maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine) which has been stable for at least four weeks, **AND**
- The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine), **AND**
- Patient must be experiencing residual moderate to severe ADHD symptoms resulting in impaired functioning (social, academic or occupational), present in at least one setting (home, nursery/school/college/work, friends or family homes or other environment).

**Population criteria:**
- Patient must be or have been diagnosed between the ages of 6 and 17 years inclusive.

---

**Authority required (STREAMLINED) 8585**

Attention deficit hyperactivity disorder

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be adjunctive to ongoing maximum tolerated dose (MTD) of stimulant (dexamfetamine, methylphenidate or lisdexamfetamine).

### guanfacine 1 mg modified release 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>125.28</td>
<td>41.00</td>
<td>Intuniv [TK]</td>
</tr>
</tbody>
</table>

### guanfacine 2 mg modified release tablet, 28

<table>
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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>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>125.28</td>
<td>41.00</td>
<td>Intuniv [TK]</td>
</tr>
</tbody>
</table>

### guanfacine 3 mg modified release tablet, 28

<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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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>125.28</td>
<td>41.00</td>
<td>Intuniv [TK]</td>
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### guanfacine 4 mg modified release tablet, 28

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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>125.28</td>
<td>41.00</td>
<td>Intuniv [TK]</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>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>19.65</td>
<td>20.94</td>
<td></td>
<td>APO-Moxonidine TX</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Moxonidine GH GQ</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Moxonidine MYL AF</td>
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<td>Physiots GQ</td>
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### moxonidine 400 microgram tablet, 30

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<td>Physiots GQ</td>
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### ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING

#### Alpha-adrenoreceptor antagonists

### PRAZOSIN

#### prazosin 1 mg tablet, 100

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<td>Minipress PF</td>
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#### prazosin 2 mg tablet, 100

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<td>Minipress PF</td>
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#### prazosin 5 mg tablet, 100

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<td>Minipress PF</td>
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### ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON

#### Hydrazinophthalazine derivatives

### HYDRALAZINE

#### hydralazine hydrochloride 25 mg tablet, 100

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#### hydralazine hydrochloride 50 mg tablet, 100

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### Pyrimidine derivatives

General Pharmaceutical Benefits 129
Minoxidil

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.

Restricted benefit
Severe refractory hypertension
Clinical criteria:
• The treatment must be initiated by a consultant physician.

minoxidil 10 mg tablet, 100

<table>
<thead>
<tr>
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Diuretics

Low-ceiling diuretics, thiazides
Thiazides, plain

Hydrochlorothiazide

hydrochlorothiazide 25 mg tablet, 100

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<td>22.49</td>
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Low-ceiling diuretics, excl. thiazides
Sulfonamides, plain

Chlortalidone

chlortalidone 25 mg tablet, 50

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Indapamide

indapamide hemihydrate 1.5 mg modified release tablet, 90

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<th>DPMQ $</th>
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<tbody>
<tr>
<td>1</td>
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<td>19.73</td>
<td>21.02</td>
<td>* APO-Indapamide SR [TX]</td>
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<td></td>
<td></td>
<td></td>
<td>* Odaplix SR [AF]</td>
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<td></td>
<td></td>
<td></td>
<td>* INADAPAMIDE AN SR [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Tenaxil SR [RW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>7.15</td>
<td>26.88</td>
<td>* Natrilix SR [SE]</td>
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indapamide hemihydrate 2.5 mg tablet, 90

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<thead>
<tr>
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<td>18.59</td>
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<td></td>
<td></td>
<td>* Indapamide AN [EA]</td>
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<td>* GenRx Indapamide [GX]</td>
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<td></td>
<td>7.58</td>
<td>24.88</td>
<td>* Insig [RW]</td>
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<td></td>
<td></td>
<td></td>
<td>* Natrilix [SE]</td>
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High-ceiling diuretics
Sulfonamides, plain

Furosemide (frusemide)

furosemide (frusemide) 20 mg/2 mL injection, 5 x 2 mL ampoules

<table>
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<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>13.34</td>
<td>14.63</td>
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furosemide (frusemide) 10 mg/mL oral liquid, 30 mL

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<th>DPMQ $</th>
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<tr>
<td>3</td>
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<td>28.04</td>
<td>29.33</td>
<td>Lasix [SW]</td>
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furosemide (frusemide) 40 mg tablet, 100

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<tbody>
<tr>
<td>1</td>
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<td>13.70</td>
<td>14.99</td>
<td>* Urex [RW]</td>
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<td></td>
<td></td>
<td>* APO-Frusemide [TX]</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Frusemix [TY]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Uremide [AF]</td>
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<td></td>
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<td>2.40</td>
<td>16.10</td>
<td>* Lasix [SW]</td>
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* Frusax [ER]
* Furosemide AN [EA]
### furosemide (frusemide) 500 mg tablet, 50

<table>
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### Furosemide (frusemide)

**Note** For item codes 2414C and 1810G, pharmaceutical benefits that have the form tablet 20 mg are equivalent for the purposes of substitution.

### furosemide (frusemide) 20 mg tablet, 50

<table>
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### furosemide (frusemide) 20 mg tablet, 100

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### Aryloxyacetic acid derivatives

### ETACYRNYC ACID

**Restricted benefit**

**Patients hypersensitive to other oral diuretics**

### etacrynic acid 25 mg tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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### POTASSIUM-SPARING AGENTS

#### Aldosterone antagonists

### Eplerenone

**Caution** Serum electrolytes should be checked regularly

**Note Continuing Therapy Only:**

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

**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.

### eplerenone 25 mg tablet, 30

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### eplerenone 50 mg tablet, 30

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</table>

### Spirolozone

**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

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### spironolactone 25 mg tablet, 100

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# DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION

**Low-ceiling diuretics and potassium-sparing agents**

## AMILORIDE + HYDROCHLOROTHIAZIDE

**Caution** Serum electrolytes should be checked regularly.

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## OTHER DIURETICS

### Vasopressin antagonists

**TOLVAPTAN**

**Caution** Tolvaptan has been associated with idiosyncratic hepatic toxicity. Liver function monitoring is required.

**Authority required**

Autosomal dominant polycystic kidney disease (ADPKD)

**Treatment Phase: Initial treatment**

**Treatment criteria:**
- Must be treated by a nephrologist.

**Clinical criteria:**
- Patient must have an estimated glomerular filtration rate (eGFR) between 30 and 89 mL/min 1.73 m² at the initiation of treatment with this drug for this condition, **AND**
- Patient must have or have had rapidly progressing disease at the time of initiation of this drug for this condition. Rapidly progressing disease is defined as either of the following:
  - A decline in eGFR of greater than or equal to 5 mL/min/1.73 m² within one year;
  - OR
  - An average decline in eGFR of greater than or equal to 2.5 mL/min/1.73 m² per year over a five year period.

<table>
<thead>
<tr>
<th>tolvaptan 30 mg tablet [28] (®) tolvaptan 60 mg tablet [28], 56</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

**TOLVAPTAN**

**Caution** Tolvaptan has been associated with idiosyncratic hepatic toxicity. Liver function monitoring is required.

**Authority required (STREAMLINED)**

8288

Autosomal dominant polycystic kidney disease (ADPKD)

**Treatment Phase: Continuing treatment**

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

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have end-stage renal disease defined as an estimated glomerular filtration rate (eGFR) of less than 15 mL/min/1.73 m², **AND**
- Patient must not have had a kidney transplant.

<table>
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<tr>
<th>tolvaptan 30 mg tablet [28] (®) tolvaptan 60 mg tablet [28], 56</th>
</tr>
</thead>
<tbody>
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## PERIPHERAL VASODILATORS

### PHENOXYBENZAMINE

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.

### Restricted Benefit
Phaeochromocytoma

### Restricted Benefit
Neurogenic urinary retention

<table>
<thead>
<tr>
<th>1862B</th>
<th>phenoxybenzamine hydrochloride 10 mg capsule, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>1</td>
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<table>
<thead>
<tr>
<th>1166J</th>
<th>phenoxybenzamine hydrochloride 10 mg capsule, 30</th>
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<tr>
<td>Max Qty Packs</td>
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## BETA BLOCKING AGENTS

### OXPRENOLOL

<table>
<thead>
<tr>
<th>2961W</th>
<th>oxprenolol hydrochloride 40 mg tablet, 100</th>
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### PINDOLOL

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<tr>
<th>3062E</th>
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### PROPRANOLOL

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<th>2565B</th>
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### ATENOLOL

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</tbody>
</table>

|       |                           | Brand Name and Manufacturer |
|       |                           | Atenol Amneal [EF] |
|       |                           | Atenol GH [GQ] |
|       |                           | Noten [AF] |
|       |                           | Tensig [RW] |
### ATENOLOL

**Restricted benefit**
For a patient who is unable to take a solid dose form of atenolol.

<table>
<thead>
<tr>
<th>atenolol 50 mg/10 mL oral liquid, 300 mL</th>
</tr>
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<tbody>
<tr>
<td>Max Qty Packs</td>
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<tr>
<td>---------------</td>
</tr>
<tr>
<td>2243C</td>
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</table>

### BISOPROLOL

**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.

**Restricted benefit**
Moderate to severe heart failure

**Clinical criteria:**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

#### bisoprolol fumarate 10 mg tablet, 28

<table>
<thead>
<tr>
<th>bisoprolol fumarate 10 mg tablet, 28</th>
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<tbody>
<tr>
<td>Max Qty Packs</td>
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#### bisoprolol fumarate 2.5 mg tablet, 28

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<th>bisoprolol fumarate 2.5 mg tablet, 28</th>
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#### bisoprolol fumarate 5 mg tablet, 28

<table>
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</table>

### METOPROLOL SUCCINATE

**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.

**Restricted benefit**
Moderate to severe heart failure

**Clinical criteria:**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

#### METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30

<table>
<thead>
<tr>
<th>METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30</th>
</tr>
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<tbody>
<tr>
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<tr>
<td>8735R</td>
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#### METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15

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<td>---------------</td>
</tr>
<tr>
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#### METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30

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<tr>
<td>8733P</td>
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#### METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30

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### METOPROLOL TARTRATE

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<table>
<thead>
<tr>
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### NEBIVOLOL

**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.

**Restricted benefit**
Moderate to severe heart failure

**Clinical criteria:**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

<table>
<thead>
<tr>
<th>nebivolol 10 mg tablet, 28</th>
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<tbody>
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<td><strong>Max Qty Packs</strong></td>
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<tr>
<td>9316H</td>
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</table>

**Alpha and beta blocking agents**

### CARVEDILOL

**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.

**Restricted benefit**
Moderate to severe heart failure

**Clinical criteria:**
- Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

<table>
<thead>
<tr>
<th>carvedilol 12.5 mg tablet, 60</th>
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<table>
<thead>
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<th>carvedilol 25 mg tablet, 60</th>
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<td><strong>Max Qty Packs</strong></td>
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<tr>
<td>8257N</td>
</tr>
</tbody>
</table>
CARDIOVASCULAR SYSTEM

8258P

CARVEDIOL Sandoz [SZ]

Dicarz [AF]

Vedirol 25 [RW]

Volirop 25 [DO]

8255L

Carvedilol Sandoz [SZ]

Dicarz [AF]

Dilatrend 25 [PB]

Vedirol 3.125 [RW]

Volirop 25 [DO]

8256M

Carvedilol 3.125 mg tablet, 30

Max Qty Packs

No. of Rpts

Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

1.. 15.06 16.35

Carvedilol AN [EA]

Vedirol 3.125 [RW]

Volirop 3.125 [DO]

Carvedilol 6.25 mg tablet, 60

Max Qty Packs

No. of Rpts

Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

1 5.. 20.63 21.92

Carvedilol AN [EA]

Dilatrend 6.25 [PB]

Vedirol 6.25 [RW]

Labetalol hydrochloride 100 mg tablet, 100

Max Qty Packs

No. of Rpts

Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

1 5.. 25.27 26.56

Presolol 100 [AF]

Trandate [AS]

Labetalol hydrochloride 200 mg tablet, 100

Max Qty Packs

No. of Rpts

Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

1 5.. 25.27 26.56

Trandate [AS]

Calcium Channel Blockers

Selective Calcium Channel Blockers with Mainly Vascular Effects

Dihydropyridine derivatives

Amlodipine

Amlodipine 5 mg tablet, 30

Max Qty Packs

No. of Rpts

Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

1 5.. 12.91 14.20

Amlodipine AN [EA]

Amlodipine GH [GQ]

APo-Amlodipine [TX]

Auro-Amlodipine 5 [DO]

BTC Amlodipine [JB]

Amlodipine 10 mg tablet, 30

Max Qty Packs

No. of Rpts

Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

1 5.. 13.60 14.89

Amlodipine AN [EA]

Amlodipine APOTEX [GX]

Auro-Amlodipine 10 [DO]

BTC Amlodipine [JB]

Amlodipine 2.5 mg modified release tablet, 30

Max Qty Packs

No. of Rpts

Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

1 5.. 16.05 17.34

Felodil XR 5 [RW]

Fendex ER [AF]

Plendil ER [GX]

Felodipine

Felodipine 5 mg modified release tablet, 30

Max Qty Packs

No. of Rpts

Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

1 5.. 16.05 17.34

Felodil XR 5 [RW]

Fendex ER [AF]

Plendil ER [GX]
### CARDIOVASCULAR SYSTEM

#### LERCANIDIPINE

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<thead>
<tr>
<th>lercanidipine hydrochloride 10 mg tablet, 28</th>
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### LERCANIDIPINE

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<tr>
<th>lercanidipine hydrochloride 20 mg tablet, 28</th>
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### SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS

#### Phenylalkylamine derivatives

<table>
<thead>
<tr>
<th>VERAPAMIL</th>
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</thead>
</table>

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

#### DILTIAZEM

**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.
diltiazem hydrochloride 240 mg modified release capsule, 30

1313D Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 ... 21.11 22.40 * Diltiazem Sandoz [SZ] * Vasocardol CD [AV]

enalapril maleate 5 mg tablet, 30

1388H Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 ... 23.01 22.40 * Cardizem CD [SW]

enalapril maleate 20 mg tablet, 30

1388H Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 5 ... 23.01 22.40 * Cardizem CD [SW]

ACE INHIBITORS, PLAIN

ACE inhibitors, plain

Captopril

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

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 ... 16.87 18.16 * Captopril Sandoz [SZ]

3.95 20.82 18.16 * Zedace [AF]

4.67 21.54 18.16 * Capoten [RW]

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 ... 21.58 22.87 * Captopril Sandoz [SZ]

3.90 25.48 22.87 * Capoten [RW]

3.94 25.52 22.87 * Zedace [AF]

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 ... 15.37 16.66 Captopril Sandoz [SZ]

Captopril

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Patients unable to take a solid dose form of an ACE inhibitor.

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 ... 107.84 41.00 Capoten [RW]

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 ... 15.11 16.40 * Acetec [AL]

* Enalapril Actavis [ED]

* Enalapril Sandoz [SZ]

* APO-Enalapril [TX]

* APO-Enalapril [GQ]

* Malean [RW]

6.40 21.51 16.40 * Renitec [AF]

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 ... 15.94 17.23 * Acetec [AL]

* Enalapril Actavis [ED]

* Enalapril Sandoz [SZ]

* APO-Enalapril [TX]

* APO-Enalapril [GQ]

* Malean [RW]

6.40 22.34 17.23 * Renitec 20 [AF]

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 ... 13.89 15.18 * Acetec [AL]

* Enalapril Actavis [ED]

* APO-Enalapril [TX]

* APO-Enalapril [GQ]

* Malean [RW]
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**

<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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<tbody>
<tr>
<td>1</td>
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<td>17.80</td>
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*Brand Name and Manufacturer*

- APO-Fosinopril [TX]
- Monace 10 [AF]

**Fosinopril Sodium 20 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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<td>20.02</td>
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</table>

*Brand Name and Manufacturer*

- APO-Fosinopril [TX]
- Monace 20 [AF]

**LISINOPRIL**

*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>
<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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*Brand Name and Manufacturer*

- APO-Lisinopril [TX]
- Auro-Lisinopril 10 [DO]
- Fibsol 10 [RW]
- Lisinopril generichealth [GQ]
- Monace 10 [AF]
- Zinopril 10 [AL]

**Lisinopril 20 mg Tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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*Brand Name and Manufacturer*

- APO-Lisinopril [TX]
- Auro-Lisinopril 20 [DO]
- Fibsol 20 [RW]
- Lisinopril generichealth [GQ]
- Monace 20 [AF]
- Zinopril 20 [AL]

**Lisinopril 5 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>
<th>MRVSN ($)</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td></td>
<td>14.18</td>
<td>15.47</td>
</tr>
</tbody>
</table>

*Brand Name and Manufacturer*

- APO-Lisinopril [TX]
- Auro-Lisinopril 5 [DO]
- Fibsol 5 [RW]
- Lisinopril generichealth [GQ]
- Monace 5 [AF]
- Zinopril 5 [AL]

**PERINDOPRIL**

*Caution* Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Perindopril Erbumine 2 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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td></td>
<td>13.56</td>
<td>14.85</td>
</tr>
</tbody>
</table>

*Brand Name and Manufacturer*

- APO-Perindopril [TX]
- Blooms the Chemist Perindopril [IB]
- BTC Perindopril [JB]
- Indosyl Mono 2 [RW]
- Perindopril Actavis 2 [EA]
- Perindopril APOTEX [TY]

**Perindopril Arginine 2.5 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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td></td>
<td>13.56</td>
<td>14.85</td>
</tr>
</tbody>
</table>

*Brand Name and Manufacturer*

- APO-Perindopril Arginine [TX]
- PREXUM 2.5 [RW]
- Coversyl 2.5mg [SE]

**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 2 mg tablet and pharmaceutical benefits that have the form perindopril arginine 2.5 mg tablet are equivalent for the purposes of substitution.

**Perindopril Erbumine 4 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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td></td>
<td>13.56</td>
<td>14.85</td>
</tr>
</tbody>
</table>

*Brand Name and Manufacturer*

- APO-Perindopril [TX]
- Blooms the Chemist Perindopril [IB]
- BTC Perindopril [JB]
- Indosyl Mono 2 [RW]
- Perindopril Actavis 2 [EA]
- Perindopril APOTEX [TY]

**Perindopril Arginine 4 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>
<td>5</td>
<td></td>
<td>13.56</td>
<td>14.85</td>
</tr>
</tbody>
</table>

*Brand Name and Manufacturer*

- APO-Perindopril Arginine [TX]
- PREXUM 4.0 [RW]
- Coversyl 4.0mg [SE]
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 8 mg tablet and pharmaceutical benefits that have the form perindopril arginine 10 mg tablet 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.

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 10 mg tablet and pharmaceutical benefits that have the form ramipril 10 mg capsule are equivalent for the purposes of substitution.
General Pharmaceutical Benefits

**TRANDOLAPRIL**

**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 trandolapril 1.25 mg capsule and pharmaceutical benefits that have the form trandolapril 1.25 mg capsule are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>MRVSN $</th>
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<tr>
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<td>APO-Trandolapril [TX]</td>
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<td>Ramace 5 mg [AV]</td>
</tr>
<tr>
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<td>22.30</td>
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<td>Trandolapril [RW]</td>
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**trandolapril 2 mg capsule, 28**

<table>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>18.09</td>
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<td>Dolapril 2 [RW]</td>
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**trandolapril 4 mg capsule, 28**

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<thead>
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<td>20.30</td>
<td>21.01</td>
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<td>Dolapril 4 [RW]</td>
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</table>

**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 1.25 mg tablet and pharmaceutical benefits that have the form ramipril 1.25 mg tablet are equivalent for the purposes of substitution.

<table>
<thead>
<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>30</td>
<td>10</td>
<td>13.04</td>
<td>14.33</td>
<td></td>
<td>APO-Ramipril [TX]</td>
</tr>
<tr>
<td>30</td>
<td>10</td>
<td>16.80</td>
<td>18.09</td>
<td></td>
<td>Ramace 2.5 mg [AV]</td>
</tr>
<tr>
<td>30</td>
<td>10</td>
<td>13.04</td>
<td>14.33</td>
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<td>Prilace [RF]</td>
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</table>

**ramipril 1.25 mg capsule, 30**

<table>
<thead>
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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>1945J</td>
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<td>14.80</td>
<td></td>
<td>APO-Ramipril [TX]</td>
</tr>
<tr>
<td>1945J</td>
<td>10</td>
<td>16.80</td>
<td>18.09</td>
<td></td>
<td>Ramipril AN [EA]</td>
</tr>
<tr>
<td>1945J</td>
<td>10</td>
<td>16.80</td>
<td>18.09</td>
<td></td>
<td>Ramipril Winthrop [WA]</td>
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<tr>
<td>1945J</td>
<td>10</td>
<td>13.51</td>
<td>14.80</td>
<td></td>
<td>Trandolapril [RW]</td>
</tr>
</tbody>
</table>

**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 5 mg tablet and pharmaceutical benefits that have the form ramipril 5 mg capsule are equivalent for the purposes of substitution.

<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>10</td>
<td>13.04</td>
<td>14.33</td>
<td></td>
<td>APO-Ramipril [TX]</td>
</tr>
<tr>
<td>30</td>
<td>10</td>
<td>16.80</td>
<td>18.09</td>
<td></td>
<td>Ramipril AN [EA]</td>
</tr>
<tr>
<td>30</td>
<td>10</td>
<td>13.04</td>
<td>14.33</td>
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<td>Prilace [RF]</td>
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**ramipril 2.5 mg capsule, 30**

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</thead>
<tbody>
<tr>
<td>1946K</td>
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<td>13.51</td>
<td>14.80</td>
<td></td>
<td>APO-Ramipril [TX]</td>
</tr>
<tr>
<td>1946K</td>
<td>10</td>
<td>16.80</td>
<td>18.09</td>
<td></td>
<td>Ramipril 5 mg [AV]</td>
</tr>
<tr>
<td>1946K</td>
<td>10</td>
<td>13.51</td>
<td>14.80</td>
<td></td>
<td>Prilace [RF]</td>
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</table>

**ramipril 5 mg capsule, 30**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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</thead>
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<tr>
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<td>APO-Ramipril [TX]</td>
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<td>10</td>
<td>16.80</td>
<td>18.09</td>
<td></td>
<td>Ramipril AN [EA]</td>
</tr>
<tr>
<td>1946K</td>
<td>10</td>
<td>13.89</td>
<td>15.18</td>
<td></td>
<td>Prilace [RF]</td>
</tr>
</tbody>
</table>

**ramipril 5 mg tablet, 30**

<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>1946K</td>
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<td>13.89</td>
<td>15.18</td>
<td></td>
<td>APO-Ramipril [TX]</td>
</tr>
<tr>
<td>1946K</td>
<td>10</td>
<td>16.80</td>
<td>18.09</td>
<td></td>
<td>Ramipril 5 mg [AV]</td>
</tr>
<tr>
<td>1946K</td>
<td>10</td>
<td>13.89</td>
<td>15.18</td>
<td></td>
<td>Prilace [RF]</td>
</tr>
</tbody>
</table>

**ramipril 2.5 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>
</tr>
</thead>
<tbody>
<tr>
<td>1946J</td>
<td>10</td>
<td>13.51</td>
<td>14.80</td>
<td></td>
<td>APO-Ramipril [TX]</td>
</tr>
<tr>
<td>1946J</td>
<td>10</td>
<td>16.80</td>
<td>18.09</td>
<td></td>
<td>Ramipril 5 mg [AV]</td>
</tr>
<tr>
<td>1946J</td>
<td>10</td>
<td>13.51</td>
<td>14.80</td>
<td></td>
<td>Prilace [RF]</td>
</tr>
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</table>

**ramipril 1.25 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>
</tr>
</thead>
<tbody>
<tr>
<td>1946J</td>
<td>10</td>
<td>13.51</td>
<td>14.80</td>
<td></td>
<td>APO-Ramipril [TX]</td>
</tr>
<tr>
<td>1946J</td>
<td>10</td>
<td>16.80</td>
<td>18.09</td>
<td></td>
<td>Ramipril 5 mg [AV]</td>
</tr>
<tr>
<td>1946J</td>
<td>10</td>
<td>13.51</td>
<td>14.80</td>
<td></td>
<td>Prilace [RF]</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>
</tr>
</thead>
<tbody>
<tr>
<td>1946J</td>
<td>10</td>
<td>13.51</td>
<td>14.80</td>
<td></td>
<td>APO-Ramipril [TX]</td>
</tr>
<tr>
<td>1946J</td>
<td>10</td>
<td>16.80</td>
<td>18.09</td>
<td></td>
<td>Ramipril 5 mg [AV]</td>
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<tr>
<td>1946J</td>
<td>10</td>
<td>13.51</td>
<td>14.80</td>
<td></td>
<td>Prilace [RF]</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dolapril 0.5 [RW]</td>
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<td>15.42</td>
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<tr>
<td>Tranalpha [AF]</td>
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</table>

### 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.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enalapril/HCT Sandoz [SZ]</td>
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<tr>
<td>Renitec Plus 20/6 [AF]</td>
<td></td>
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<td>6.99</td>
</tr>
</tbody>
</table>

### PERINDOPRIL + INDAPAMIDE

**Caution**: Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30**

**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.

**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.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>PREXUM Combi LD 2.5/0.625</td>
<td>7.88</td>
<td>21.88</td>
<td>7.14</td>
</tr>
<tr>
<td>Coversyl Plus LD 2.5mg/0.625mg [SE]</td>
<td>15.76</td>
<td>17.05</td>
<td>7.14</td>
</tr>
</tbody>
</table>

**perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30**

**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.

**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.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prexum Combi 5/1.25 [RW]</td>
<td>15.76</td>
<td>17.05</td>
<td></td>
</tr>
<tr>
<td>Coversyl Plus 5mg/1.25mg [SE]</td>
<td>22.90</td>
<td>17.05</td>
<td>7.14</td>
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</table>
**CARDIOVASCULAR SYSTEM**

**General Pharmaceutical Benefits**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>GenRx Perindopril/Indapamide 4/1.25 [GX]</td>
<td>Idaprex Combi 4/1.25 [SZ]</td>
<td>1</td>
<td>15.76</td>
<td>17.05</td>
<td></td>
</tr>
<tr>
<td>Indosyl Combi 4/1.25 [RW]</td>
<td>Perindopril and Indapamide AN 4/1.25 [EF]</td>
<td>1</td>
<td>17.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perindopril Combi Actavis 4/1.25 [ED]</td>
<td>Perindopril/Indapamide GH 4/1.25 [GG]</td>
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<td>17.05</td>
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</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>Brand Name and Manufacturer</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
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<tbody>
<tr>
<td>Zan-Extra 10/10 [GO]</td>
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<td>Accuretic 10/12.5mg [PF]</td>
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<td>19.80</td>
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</tbody>
</table>

**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>Brand Name and Manufacturer</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zan-Extra 10/10 [GO]</td>
<td>1</td>
<td>17.00</td>
<td>18.29</td>
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</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 amiodipine at the same doses.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>APO-Perindopril Arginine/Amlodipine 10/10 [TX]</td>
<td>1</td>
<td>7.90</td>
<td>25.88</td>
<td>19.27</td>
</tr>
<tr>
<td>Reaptan 10/10 [RW]</td>
<td>1</td>
<td>17.98</td>
<td>19.27</td>
<td></td>
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<tr>
<td>Coveram 10/10 [SE]</td>
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<td>17.98</td>
<td>19.27</td>
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</table>

General Pharmaceutical Benefits
### CARDIOVASCULAR SYSTEM

#### perindopril arginine 10 mg + amlodipine 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>
</tr>
</thead>
<tbody>
<tr>
<td>9348B</td>
<td>1</td>
<td>17.29</td>
<td>18.58</td>
<td></td>
<td>APO-Perindopril Arginine/Amlodipine 10/5 [TX]</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>24.88</td>
<td>18.58</td>
<td></td>
<td>Reaptan 10/5 [RW]</td>
</tr>
</tbody>
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#### perindopril arginine 5 mg + amlodipine 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>9347Y</td>
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<td>17.75</td>
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<td>5</td>
<td>23.90</td>
<td>17.75</td>
<td></td>
<td>Reaptan 5/10 [RW]</td>
</tr>
</tbody>
</table>

#### perindopril arginine 5 mg + amlodipine 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>
</tr>
</thead>
<tbody>
<tr>
<td>9346X</td>
<td>1</td>
<td>15.77</td>
<td>17.06</td>
<td></td>
<td>APO-Perindopril Arginine/Amlodipine 5/5 [TX]</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>22.90</td>
<td>17.06</td>
<td></td>
<td>Reaptan 5/5 [RW]</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.

#### ramipril 2.5 mg + felodipine 2.5 mg modified release 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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</thead>
<tbody>
<tr>
<td>2626F</td>
<td>1</td>
<td>16.32</td>
<td>17.61</td>
<td></td>
<td>Triasyn 2.5/2.5 [SW]</td>
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#### ramipril 5 mg + felodipine 5 mg modified release 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>2629J</td>
<td>1</td>
<td>17.92</td>
<td>19.21</td>
<td></td>
<td>Triasyn 5.0/5.0 [SW]</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.

The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

**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.

#### trandolapril 2 mg + verapamil hydrochloride 180 mg modified release 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>9387C</td>
<td>1</td>
<td>22.44</td>
<td>23.73</td>
<td></td>
<td>Tarka 2/180 [GO]</td>
</tr>
</tbody>
</table>

#### trandolapril 4 mg + verapamil hydrochloride 240 mg modified release 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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<tr>
<td>2857J</td>
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### ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN

#### Angiotensin II receptor blockers (ARBs), plain

#### CANDESARTAN

candesartan cilexetil 16 mg tablet, 30

<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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<tr>
<td>8297Q</td>
<td>1</td>
<td>16.15</td>
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<td>APO-Candesartan [TX]</td>
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</tbody>
</table>
- Adesan [AF]
- Blooms the Chemist Candesartan [IB]
- Candesartan AN [EA]
- Candesartan GH [GQ]
- Candesartan Aspen 16 [RW]
- Candesartan Sandoz [SZ]

|               | 5           | 29.62     | 17.44  |         | Atacand [AP]                |

144 Schedule of Pharmaceutical Benefits – December 2020
### General Pharmaceutical Benefits

**Candesartan Cilexetil 32 mg Tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
<td>1</td>
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<td>..</td>
<td>17.01</td>
<td>18.30</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td><em>Adesan [AF]</em></td>
<td><em>APO-Candesartan [TX]</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>Bloom's the Chemist</em></td>
<td><em>CANDESARAN [RF]</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>Candesartan [IB]</em></td>
<td><em>Candesartan [IB]</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>Candesartan AN [EA]</em></td>
<td><em>Candesartan [IB]</em></td>
</tr>
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<td></td>
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<td><em>Candesartan GH [GQ]</em></td>
<td><em>Candesartan [IB]</em></td>
</tr>
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<td></td>
<td><em>Candesartan Sandoz [SZ]</em></td>
<td><em>Candesartan [IB]</em></td>
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</table>

**Candesartan Cilexetil 4 mg Tablet, 30**

<table>
<thead>
<tr>
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<td>12.48</td>
<td>13.77</td>
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<td></td>
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<td><em>Adesan [AF]</em></td>
<td><em>APO-Candesartan [TX]</em></td>
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<tr>
<td></td>
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<td><em>Bloom's the Chemist</em></td>
<td><em>CANDESARAN [RF]</em></td>
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<tr>
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<td><em>Candesartan [IB]</em></td>
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<td></td>
<td><em>Candesartan AN [EA]</em></td>
<td><em>Candesartan [IB]</em></td>
</tr>
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<td><em>Candesartan Sandoz [SZ]</em></td>
<td><em>Candesartan [IB]</em></td>
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</table>

**Candesartan Cilexetil 8 mg Tablet, 30**

<table>
<thead>
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<tr>
<td>1</td>
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<td>13.47</td>
<td>14.70</td>
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<td></td>
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<td><em>Adesan [AF]</em></td>
<td><em>APO-Candesartan [TX]</em></td>
</tr>
<tr>
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<td><em>Bloom's the Chemist</em></td>
<td><em>CANDESARAN [RF]</em></td>
</tr>
<tr>
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<td><em>Candesartan [IB]</em></td>
<td><em>Candesartan [IB]</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>Candesartan AN [EA]</em></td>
<td><em>Candesartan [IB]</em></td>
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<tr>
<td></td>
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<td></td>
<td><em>Candesartan Sandoz [SZ]</em></td>
<td><em>Candesartan [IB]</em></td>
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</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>
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<tbody>
<tr>
<td>8397Y</td>
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<td>2</td>
<td>5</td>
<td>7.00</td>
<td>31.38</td>
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<td></td>
<td></td>
<td></td>
<td>Teveten [GO]</td>
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</tr>
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</table>

**Eprosartan 600 mg Tablet, 28**

<table>
<thead>
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<td>1</td>
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<td></td>
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<td>Teveten [GO]</td>
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### Irbesartan

**Irbesartan 150 mg Tablet, 30**

<table>
<thead>
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<th>No. of Rpts</th>
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<td>8247C</td>
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<td><em>Abisart 150 [AL]</em></td>
<td><em>APO-Irbesartan [TX]</em></td>
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<tr>
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<td></td>
<td><em>AVSARTAN [RF]</em></td>
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<td><em>Irbesartan Actavis 150 [ED]</em></td>
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<td><em>Irbesartan AN [EA]</em></td>
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<td><em>Irbesartan Sandoz [SZ]</em></td>
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</table>

**Irbesartan 300 mg Tablet, 30**

<table>
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<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>17.00</td>
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<td><em>Abisart 300 [AL]</em></td>
<td><em>APO-Irbesartan [TX]</em></td>
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</table>
## Cardiovacular System

### Irbesartan

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>Avapro [AV]</td>
<td>13.31</td>
<td>14.60</td>
</tr>
<tr>
<td>Karvea [SW]</td>
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<td>14.60</td>
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</table>

### Losartan

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>Cozavan [AF]</td>
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<td>15.08</td>
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</tbody>
</table>

### Olmesartan

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olmetec [AL]</td>
<td>17.16</td>
<td>18.45</td>
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### Telmisartan

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micardis [BY]</td>
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</tbody>
</table>

### Valsartan

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diovan [NV]</td>
<td>21.20</td>
<td>22.49</td>
</tr>
</tbody>
</table>
### CARDIOVASCULAR SYSTEM

#### General Pharmaceutical Benefits

- **Valsartan 40 mg tablet, 28**
  - **9368C**
    - Max Qty Packs: 1
    - No. of Rpts: ..
    - Premium $: 16.92
    - DPMQ $: 18.21
    - MRVSN $: * Dilart [AF]
    - Brand Name and Manufacturer: * Dilart [AF]
    - Brand Name and Manufacturer: * Diovon [NV]

- **Valsartan 80 mg tablet, 28**
  - **9369D**
    - Max Qty Packs: 1
    - No. of Rpts: 5
    - Premium $: 19.17
    - DPMQ $: 20.46
    - MRVSN $: * Dilart [AF]
    - Brand Name and Manufacturer: * Dilart [AF]
    - Brand Name and Manufacturer: * Diovon [NV]

#### Valsartan

**Note:** No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

- **Valsartan 320 mg tablet, 28**
  - **9371F**
    - Max Qty Packs: 1
    - No. of Rpts: 5
    - Premium $: 23.79
    - DPMQ $: 25.08
    - MRVSN $: * Dilart [AF]
    - Brand Name and Manufacturer: * Dilart [AF]
    - Brand Name and Manufacturer: * Diovon [NV]

#### Angiotensin II Receptor Blockers (ARBs), Combinations

**Angiotensin II receptor blockers (ARBs) 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**
  - **8504N**
    - Max Qty Packs: 1
    - No. of Rpts: 5
    - Premium $: 16.45
    - DPMQ $: 17.74
    - MRVSN $: * Adesan HCT 16/12.5 [AF]
    - Brand Name and Manufacturer: * Adesan HCT 16/12.5 [AF]
    - Brand Name and Manufacturer: * APO-Candesartan HCTZ 16/12.5 [TX]
    - Brand Name and Manufacturer: * Asartan HCT 16/12.5 [DO]
    - Brand Name and Manufacturer: * Blooms the Chemist Candesartan HCTZ 16/12.5 [IB]
    - Brand Name and Manufacturer: * CANDESAN COMBI 16/12.5 [RF]
    - Brand Name and Manufacturer: * Candesartan Combi Aspen 16/12.5 [IB]
    - Brand Name and Manufacturer: * Candesartan HCT GH 16/12.5 [GO]
    - Brand Name and Manufacturer: * Candesartan HCTAN 16/12.5 [EA]
    - Brand Name and Manufacturer: * Candesartan HCTZ 16/12.5 [IB]
    - Brand Name and Manufacturer: * Candesartan HCTZ AN 16/12.5 [EA]
    - Brand Name and Manufacturer: * AP-Candesartan HCTZ 16/12.5 [IB]
    - Brand Name and Manufacturer: * Atacand Plus 16/12.5 [AP]

- **Candesartan Cilexetil 32 mg + Hydrochlorothiazide 12.5 mg tablet, 30**
  - **9314F**
    - Max Qty Packs: 1
    - No. of Rpts: 5
    - Premium $: 17.20
    - DPMQ $: 18.49
    - MRVSN $: * Adesan HCT 32/12.5 [AF]
    - Brand Name and Manufacturer: * Adesan HCT 32/12.5 [AF]
    - Brand Name and Manufacturer: * APO-Candesartan HCTZ 32/12.5 [TX]
    - Brand Name and Manufacturer: * Asartan HCT 32/12.5 [DO]
    - Brand Name and Manufacturer: * Blooms the Chemist Candesartan HCTZ 32/12.5 [IB]
    - Brand Name and Manufacturer: * CANDESAN COMBI 32/12.5 [RF]
    - Brand Name and Manufacturer: * Candesartan Combi Aspen 32/12.5 [IB]
    - Brand Name and Manufacturer: * Candesartan HCT GH 32/12.5 [GO]
    - Brand Name and Manufacturer: * Candesartan HCTAN 32/12.5 [EA]
    - Brand Name and Manufacturer: * Candesartan HCTZ 32/12.5 [IB]
    - Brand Name and Manufacturer: * Candesartan HCTZ AN 32/12.5 [EA]
    - Brand Name and Manufacturer: * AP-Candesartan HCTZ 32/12.5 [IB]
    - Brand Name and Manufacturer: * Atacand Plus 32/12.5 [AP]

- **Candesartan Cilexetil 32 mg + Hydrochlorothiazide 25 mg tablet, 30**
  - **9315G**
    - Max Qty Packs: 1
    - No. of Rpts: 5
    - Premium $: 18.03
    - DPMQ $: 19.32
    - MRVSN $: * Adesan HCT 32/25 [AF]
    - Brand Name and Manufacturer: * Adesan HCT 32/25 [AF]
    - Brand Name and Manufacturer: * APO-Candesartan HCTZ 32/25 [TX]
    - Brand Name and Manufacturer: * Asartan HCT 32/25 [DO]
    - Brand Name and Manufacturer: * Blooms the Chemist Candesartan HCTZ 32/25 [IB]
    - Brand Name and Manufacturer: * CANDESAN COMBI 32/25 [RF]
    - Brand Name and Manufacturer: * Candesartan Combi Aspen 32/25 [IB]
    - Brand Name and Manufacturer: * Candesartan HCT GH 32/25 [GO]
    - Brand Name and Manufacturer: * Candesartan HCTAN 32/25 [EA]
    - Brand Name and Manufacturer: * Candesartan HCTZ 32/25 [IB]
    - Brand Name and Manufacturer: * Candesartan HCTZ AN 32/25 [EA]
    - Brand Name and Manufacturer: * AP-Candesartan HCTZ 32/25 [IB]
    - Brand Name and Manufacturer: * Atacand Plus 32/25 [AP]
CARDIOVASCULAR SYSTEM

**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*

<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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</table>

**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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<tr>
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*Irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30*

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<td>Blooms the Chemist Irbesartan HCTZ 300/12.5 [IB]</td>
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*Irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30*

<table>
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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*

<table>
<thead>
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<th>No. of Rpts</th>
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CARDIOVASCULAR SYSTEM

General Pharmaceutical Benefits

### Olmesartan/HCTZ
- **20/12.5 CR**
  - Brand Name and Manufacturer: Pharmacor Olmesartan HCTZ 20/12.5 [CR]
- **20/12.5 [TX]**
  - Brand Name and Manufacturer: Olmertan Combi 40/12.5 [RW]
- **40/12.5 [TX]**
  - Brand Name and Manufacturer: OLMERTAN COMBI 40/12.5 [AF]
- **40/12.5 [CR]**
  - Brand Name and Manufacturer: Pharmacor Olmesartan HCTZ 40/12.5 [CR]

### Telmisartan/HCTZ
- **40/12.5 [TX]**
  - Brand Name and Manufacturer: Mizart HCT 40/12.5 mg [AF]
- **40/12.5 [GQ]**
  - Brand Name and Manufacturer: Telmisartan HCTZ AN 40/12.5 [EA]
- **40/12.5 [RW]**
  - Brand Name and Manufacturer: Teltartan HCT 40/12.5 [RW]

### Valsartan/HCTZ
- **80/12.5 [TX]**
  - Brand Name and Manufacturer: Mizar HCT 80/12.5 mg [AF]
- **80/12.5 [GQ]**
  - Brand Name and Manufacturer: Telmisartan/HCT Sandoz [SZ] [GA]
- **80/25 [TX]**
  - Brand Name and Manufacturer: Mizar HCT 80/25 mg [AF]

### Restricted Benefit

**Telmisartan + Hydrochlorothiazide**

- **Telmisartan 40 mg + Hydrochlorothiazide 12.5 mg tablet, 28**
  - Brand Name and Manufacturer: Micardis Plus 40/12.5 mg [BY]
  - Brand Name and Manufacturer: Telmisartan HCT 40/12.5 mg [AF]

**Valsartan + Hydrochlorothiazide**

- **Valsartan 160 mg + Hydrochlorothiazide 12.5 mg tablet, 28**
  - Brand Name and Manufacturer: Telmisartan HCT 80/25 mg [AF]

**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.

---

General Pharmaceutical Benefits 149
### Cardiovascular System

**Valsartan + Hydrochlorothiazide**

*Note: No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.*

#### Restricted Benefit

**Hypertension**

**Clinical criteria:**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; **OR**
- The condition must be inadequately controlled with a thiazide diuretic.

**Valsartan 160 mg + Hydrochlorothiazide 25 mg tablet, 28**

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**Valsartan 80 mg + Hydrochlorothiazide 12.5 mg tablet, 28**

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*Co-Diovan 80/12.5 [NV]  Dilart HCT 80/12.5 [AF]*

**Valsartan 320 mg + Hydrochlorothiazide 12.5 mg tablet, 28**

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*Co-Diovan 320/12.5 [NV]  Dilart HCT 320/12.5 [AF]*

**Valsartan 320 mg + Hydrochlorothiazide 25 mg tablet, 28**

<table>
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*Co-Diovan 320/25 [NV]  Dilart HCT 320/25 [AF]*

**Angiotensin II receptor blockers (ARBs) 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**

<table>
<thead>
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<th>Max Qty Packs</th>
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*Valsartan/Amlodipine Novartis 160/10 [NM]*

**Amlodipine 10 mg + Valsartan 320 mg tablet, 28**

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*Valsartan/Amlodipine Novartis 320/10 [NM]*

**Amlodipine 5 mg + Valsartan 160 mg tablet, 28**

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*Valsartan/Amlodipine Novartis 160/5 [NM]*

**Amlodipine 5 mg + Valsartan 320 mg tablet, 28**

<table>
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<th>No. of Rpts</th>
<th>Premium $</th>
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*Valsartan/Amlodipine Novartis 320/5 [NM]*

**Amlodipine 5 mg + Valsartan 80 mg tablet, 28**

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*Valsartan/Amlodipine Novartis 80/5 [NM]*

**Olmesartan Medoxomil + Amlodipine**

**Restricted Benefit**

**Hypertension**

**Clinical criteria:**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
### CARDIOVASCULAR SYSTEM

#### General Pharmaceutical Benefits

- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

<table>
<thead>
<tr>
<th>olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30</th>
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<td><strong>5292M</strong></td>
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<th>olmesartan medoxomil 40 mg + amlodipine 10 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 receptor blockers (ARBs), 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>
<thead>
<tr>
<th>amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28</th>
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</thead>
<tbody>
<tr>
<td><strong>5288H</strong></td>
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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

10005N

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

1  5  ..  18.60  19.89  * APO-Olmekar HCT 20/5/12.5 [RF]

olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30

2880N

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

1  5  ..  23.22  24.51  * APO-Olmekar HCT 40/5/12.5 [RF]

olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30

2836G

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

1  5  ..  23.91  25.20  * APO-Olmekar HCT 40/10/12.5 [RF]

olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30

2864R

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

1  5  ..  24.79  26.08  * APO-Olmekar HCT 40/5/25 [RF]

olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30

2953K

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

1  5  ..  25.48  26.77  * APO-Olmekar HCT 40/10/25 [RF]

SACUBITRIL + VALSARTAN

Note Continuing Therapy Only:

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

Note Special Pricing Arrangements apply.
CARDIOVASCULAR SYSTEM

Authority required (STREAMLINED)
6915
Chronic heart failure

Clinical criteria:

- Patient must be symptomatic with NYHA classes II, III or IV, AND
- Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%, 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, AND
- Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
- Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated, AND
- The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist.

sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56

<table>
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<th>DPMQ</th>
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sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56

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sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56

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LIPID MODIFYING AGENTS

LIPID MODIFYING AGENTS, PLAIN

HMG CoA reductase inhibitors

ATORVASTATIN

atorvastatin 10 mg tablet, 30

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<td>* Lipitor [UJ]</td>
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atorvastatin 20 mg tablet, 30

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atorvastatin 80 mg tablet, 30

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### ATORVASTATIN

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

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

**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.

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### FLUVASTATIN

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### FLUVASTATIN

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

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

**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.

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### PRAVASTATIN

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### PRAVASTATIN

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

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

### 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.

### ROSUVASTATIN

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<td>Cavstat [AF]</td>
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<td>rosuvastatin sodium 80 mg tablet, 30</td>
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<td>Crouva 10 [RW]</td>
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### Schedule of Pharmaceutical Benefits – December 2020

#### General

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<tr>
<td>Rosuvastatin generichealth [HQ]</td>
<td>Rosuvastatin RBX [RA]</td>
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<tr>
<td>Rosuvastatin Sandoz [SZ]</td>
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### ROSUVASTATIN

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

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

**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.

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<td>Rosuvastatin Sandoz [SZ]</td>
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**Note** No increase in the maximum quantity or number of units may be authorised.

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**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.

### ROSUVASTATIN

#### ROSUVASTATIN

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

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

**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.
## CARDIOVASCULAR SYSTEM

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<td>* Cavstat [AF]</td>
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<td>* Crosva 20 [RW]</td>
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### Simvastatin

#### Simvastatin 10 mg tablet, 30

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#### Simvastatin 20 mg tablet, 30

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#### Simvastatin 40 mg tablet, 30

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<td>* Zocor [MQ]</td>
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#### Simvastatin 5 mg tablet, 30

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simvastatin 80 mg tablet, 30  
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**SIMVASTATIN**  

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

**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.

simvastatin 10 mg tablet, 30  
9242K  

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simvastatin 20 mg tablet, 30  
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simvastatin 40 mg tablet, 30  
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simvastatin 5 mg tablet, 30  
9241J  

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<td>* Zimstat [AF]</td>
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Fibrates

**FENOFIBRATE**  

**Note** The risk of serious muscle toxicity is increased if this drug 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  
9023X  

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fenofibrate 48 mg tablet, 60  
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FENOFIBRATE

Note: The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

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

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.

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GEMFIBROZIL

Note: The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

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

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

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.

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Bile acid sequestrants

COLESTYRAMINE

colestyramine 4 g powder for oral liquid, 50 sachets

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COLESTYRAMINE

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

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

Restricted benefit
Primary hypercholesterolaemia

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.

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Other lipid modifying agents
EVOLOCUMAB

Note: No increase in the maximum number of repeats may be authorised.
Note: Special Pricing Arrangements apply.

Authority required (STREAMLINED)
10388
Familial homozygous hypercholesterolaemia
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be in conjunction with dietary therapy and exercise.

Evolocumab 140 mg/mL injection, 1 mL pen device

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Evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge

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EVOLOCUMAB

Note: No increase in the maximum number of repeats may be authorised.
Note: No increase in the maximum number of units may be authorised.
Note: Special Pricing Arrangements apply.

Authority required (STREAMLINED)
10385
Non-familial hypercholesterolaemia
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be in conjunction with dietary therapy and exercise.

Authority required (STREAMLINED)
10377
Familial heterozygous hypercholesterolaemia
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be in conjunction with dietary therapy and exercise.

Evolocumab 140 mg/mL injection, 1 mL pen device

<table>
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<tr>
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Evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge

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EVOLOCUMAB

Note: No increase in the maximum number of repeats may be authorised.
Note: Special Pricing Arrangements apply.
Note: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Familial homozygous hypercholesterolaemia
Treatment Phase: Initial treatment
Clinical criteria:
- The treatment must be in conjunction with dietary therapy and exercise, AND
- The condition must have been confirmed by genetic testing; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7, AND
- Patient must have an LDL cholesterol level in excess of 2.6 millimoles per litre, AND
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information.
Treatment criteria:
- Must be treated by a specialist physician.
  The qualifying LDL cholesterol level following at least 12 consecutive weeks of treatment with a statin (unless treatment with a statin is contraindicated or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.
  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.
  The following must be stated at the time of application and documented in the patient's medical records:
  (i) the qualifying Dutch Lipid Clinic Network Score; or
  (ii) the result of genetic testing confirming a diagnosis of familial homozygous hypercholesterolaemia
  One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:
  (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or
  (ii) the dose, duration of treatment and details of adverse events experienced with the trial of atorvastatin or rosuvastatin; or
  (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information

Authority required
Familial homozygous hypercholesterolaemia
Treatment Phase: Grandfather treatment
Clinical criteria:
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2020, AND
- The treatment must be in conjunction with dietary therapy and exercise, AND
- The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7 prior to starting non-PBS-subsidised treatment with this drug for this condition, AND
- Patient must have had an LDL cholesterol level in excess of 2.6 millimoles per litre prior to starting non-PBS-subsidised treatment with this drug for this condition, AND
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information.

Treatment criteria:
- Must be treated by a specialist physician.
  The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of treatment with a statin (unless treatment with a statin is contraindicated or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated.
  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.
  The following must be stated at the time of application and documented in the patient's medical records:
  (i) the qualifying Dutch Lipid Clinic Network Score; or
  (ii) the result of genetic testing confirming a diagnosis of familial homozygous hypercholesterolaemia
  One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:
  (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or
  (ii) the dose, duration of treatment and details of adverse events experienced with the trial of atorvastatin or rosuvastatin; or
  (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.
A patient 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.

**EVOLOCUMAB**

**evolocumab 140 mg/mL injection, 1 mL pen device**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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**evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge**

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<td>41.00 Repatha [AN]</td>
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**Authority required**

Familial heterozygous hypercholesterolaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- The condition must have been confirmed by genetic testing; **OR**
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6, **AND**
- Patient must have an LDL cholesterol level in excess of 2.6 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; **OR**
- Patient must have an LDL cholesterol level in excess of 5 millimoles per litre, **AND**
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; **OR**
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; **OR**
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, **AND**
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise.

**Treatment criteria:**

- Must be treated by a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or

(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or

(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient’s medical records and must be no more than 8 weeks old.

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.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

The following must be stated at the time of application and documented in the patient’s medical records:
One of the following must be stated at the time of application and documented in the patient's medical records regarding the recommended or maximum tolerated dose has been reached or target LDL.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin and continued 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; or

(i) the qualifying Dutch Lipid Clinic Network Score; or

(ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia

All of the following must be stated at the time of application and documented in the patient's medical records:

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or

(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or

(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

Authority required

Non-familial hypercholesterolaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have symptomatic atherosclerotic cardiovascular disease, AND
- Patient must have an LDL cholesterol level in excess of 2.6 millimoles per litre, AND
- Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); OR
- Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; OR
- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher, AND
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, AND
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise.

Treatment criteria:

- Must be treated by a specialist physician.
- Symptomatic atherosclerotic cardiovascular disease is defined as:
  - the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or
  - the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or
  - the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.

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.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR
- Patient must have diabetes mellitus with microalbuminuria; OR
- Patient must have diabetes mellitus and be aged 60 years or more; OR
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
- Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher, AND
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR
- Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, AND
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise.

Treatment criteria:

- Must be treated by a specialist physician.
- Symptomatic atherosclerotic cardiovascular disease is defined as:
  - the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or
  - the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or
  - the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old.

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.

If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal.

In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved.

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:
CARDIOVASCULAR SYSTEM

(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or
(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or
(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:

(i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or
(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or
(iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or
(iv) diabetes mellitus with microalbuminuria; or
(v) diabetes mellitus and age 60 years of more; or
(vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or
(vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher

Authority required
Familial heterozygous hypercholesterolaemia
Treatment Phase: Grandfather treatment

Clinical criteria:
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2020, AND
- The treatment must be in conjunction with dietary therapy and exercise, AND
- The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6 prior to starting non-PBS-subsidised treatment with this drug for this condition, AND
- Patient must have had an LDL cholesterol level in excess of 2.6 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease at the time non-PBS-subsidised treatment with this drug for this condition was initiated; OR
- Patient must have had an LDL cholesterol level in excess of 5 millimoles per litre at the time non-PBS-subsidised treatment with this drug for this condition was initiated, AND
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, AND
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition.

Treatment criteria:
- Must be treated by a specialist physician.

Symptomatic atherosclerotic cardiovascular disease is defined as:

(i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or
(ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or
(iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated.

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.

If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retiral should have occurred
after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the trial should not have occurred until CK had returned to normal.

In the event of a trial of the alternative statin, the dose of the alternative statin should have been increased not more often than every 4 weeks until the maximum tolerated dose was reached or target LDL-c had been achieved.

The following must be stated at the time of application and documented in the patient's medical records:

(i) the qualifying Dutch Lipid Clinic Network Score; or
(ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:

(i) the patient was treated with atorvastatin 80 mg or rosvustatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or
(ii) the doses, duration of treatment and details of adverse events experienced with trials of each of atorvastatin and rosvustatin; or
(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

A patient may qualify for PBS-subsidised treatment under this restriction only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Authority required
Non-familial hypercholesterolaemia

Treatment Phase: Grandfather treatment

Clinical criteria:

- The treatment must be in conjunction with dietary therapy and exercise, AND
- Patient must have had symptomatic atherosclerotic cardiovascular disease prior to starting non-PBS-subsidised treatment with this drug for this condition, AND
- Patient must have had an LDL cholesterol level in excess of 2.6 millimoles per litre prior to starting non-PBS-subsidised treatment with this drug for this condition, AND
- Patient must have had atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories) prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had diabetes mellitus with microalbuminuria prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had diabetes mellitus and be aged 60 years of more prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have been an Aboriginal or Torres Strait Islander with diabetes mellitus that was present prior to starting non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had a Thrombolysis in Myocardial Infarction (TIMI) Risk Score for Secondary Prevention of 4 or higher prior to starting non-PBS-subsidised treatment with this drug for this condition, AND
- Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information, AND
- Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a specialist physician.
- Symptomatic atherosclerotic cardiovascular disease is defined as:
  (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or
  (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or
  (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).

The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated.
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.

If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This re trials should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the re trial should not have occurred until CK had returned to normal.

In the event of a trial of the alternative statin, the dose of the alternative statin should have been increased not more often than every 4 weeks until the maximum tolerated dose was reached or target LDL-C had been achieved.

One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:
(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or
(ii) the doses, duration of treatment and details of adverse events experienced with trials of atorvastatin and rosuvastatin; or
(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.

One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event:
(i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or
(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or
(iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or
(iv) diabetes mellitus with microalbuminuria; or
(v) diabetes mellitus and age 60 years of more; or
(vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or
(vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher.

A patient 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.

evolocumab 140 mg/mL injection, 1 mL pen device
11484K

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- **EZETIMIBE**

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

  **Authority required (STREAMLINED) 7990**
  Hypercholesterolaemia
  **Clinical criteria:**
  - Patient must have homozygous sitosterolaemia.

  ezetimibe 10 mg tablet, 30
11408K

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- **EZETIMIBE**

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

  **Authority required (STREAMLINED) 7996**
  Hypercholesterolaemia
  **Clinical criteria:**

Schedule of Pharmaceutical Benefits – December 2020
The treatment must be in conjunction with dietary therapy and exercise, **AND**

The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**

Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**

- Patient must have coronary heart disease; **OR**
- Patient must have cerebrovascular disease; **OR**
- Patient must have peripheral vascular disease; **OR**
- Patient must have diabetes mellitus with microalbuminuria; **OR**
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; **OR**
- Patient must have diabetes mellitus and be aged 60 years or more; **OR**
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; **OR**
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; **OR**
- Patient must have heterozygous familial hypercholesterolaemia; **OR**
- Patient must have homozygous familial hypercholesterolaemia; **OR**
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated.

The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

### Authority required (STREAMLINED)

**7966**

**Hypercholesterolaemia**

**Clinical criteria:**

- 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; **OR**
- Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of the statin treatment; **OR**
- Patient must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated, **AND**
- Patient must have coronary heart disease; **OR**
- Patient must have cerebrovascular disease; **OR**
- Patient must have peripheral vascular disease; **OR**
- Patient must have diabetes mellitus with microalbuminuria; **OR**
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; **OR**
- Patient must have diabetes mellitus and be aged 60 years or more; **OR**
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; **OR**
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; **OR**
- Patient must have heterozygous familial hypercholesterolaemia; **OR**
- Patient must have homozygous familial hypercholesterolaemia; **OR**
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

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.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient’s medical records.

### ezetimibe 10 mg tablet, 30

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<th>Brand Name and Manufacturer</th>
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<td>Blooms The Chemist</td>
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<td>Ezetimibe GH [GQ]</td>
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<td></td>
<td>Ezetimibe Sandoz [SZ]</td>
<td>Pharmacor Ezetimibe 10 [CR]</td>
</tr>
</tbody>
</table>
LIPID MODIFYING AGENTS, COMBINATIONS

HMG CoA reductase inhibitors in combination with other lipid modifying agents

- **EZETIMIBE (&) ROSUVASTATIN**

  **Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

  **Note Continuing Therapy Only:**

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  **Authority required (STREAMLINED)**

  7957

  Hypercholesterolaemia

  **Clinical criteria:**

  - The treatment must be in conjunction with dietary therapy and exercise, **AND**
  - Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
  - Patient must have coronary heart disease; OR
  - Patient must have cerebrovascular disease; OR
  - Patient must have peripheral vascular disease; OR
  - Patient must have diabetes mellitus with microalbuminuria; OR
  - Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR
  - Patient must have diabetes mellitus and be aged 60 years or more; OR
  - Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; OR
  - Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; OR
  - Patient must have heterozygous familial hypercholesterolaemia; OR
  - Patient must have homozygous familial hypercholesterolaemia; OR
  - Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

  Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin. The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.

  The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

  Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

  **ezetimibe 10 mg tablet [30] (&) rosuvastatin 20 mg tablet [30], 60**

  10201X

  **Brand Name and Manufacturer**

  ‡1

  5

  ..

  29.18

  30.47

  a Ezalo Composite Pack

  10mg+20mg [AF]

  $3.00

  32.18

  30.47

  a Rosuzet Composite Pack [AL]

  **ezetimibe 10 mg tablet [30] (&) rosuvastatin 40 mg tablet [30], 60**

  10207F

  **Brand Name and Manufacturer**

  ‡1

  5

  ..

  30.67

  31.96

  a Ezalo Composite Pack

  10mg+40mg [AF]

  $3.00

  33.67

  31.96

  a Rosuzet Composite Pack [AL]

  **ezetimibe 10 mg tablet [30] (&) rosuvastatin 10 mg tablet [30], 60**

  10208G

  **Brand Name and Manufacturer**

  ‡1

  5

  ..

  28.17

  29.46

  a Ezalo Composite Pack

  10mg+10mg [AF]

  $3.00

  31.17

  29.46

  a Rosuzet Composite Pack [AL]

- **EZETIMIBE (&) ROSUVASTATIN**

  **Note Continuing Therapy Only:**

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

  **Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

  **Authority required (STREAMLINED)**

  7958

  Hypercholesterolaemia

  **Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise, **AND**

- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **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, **AND**
- Patient must have coronary heart disease; **OR**
- Patient must have cerebrovascular disease; **OR**
- Patient must have peripheral vascular disease; **OR**
- Patient must have diabetes mellitus with microalbuminuria; **OR**
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; **OR**
- Patient must have diabetes mellitus and be aged 60 years or more; **OR**
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; **OR**
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; **OR**
- Patient must have heterozygous familial hypercholesterolaemia; **OR**
- Patient must have homozygous familial hypercholesterolaemia; **OR**
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

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.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

### EZE TIMIBE + ATORVASTATIN

**Note** The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

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**Authority required (STREAMLINED)**

7957

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
- Patient must have coronary heart disease; **OR**
- Patient must have cerebrovascular disease; **OR**
- Patient must have peripheral vascular disease; **OR**
- Patient must have diabetes mellitus with microalbuminuria; **OR**
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; **OR**
- Patient must have diabetes mellitus and be aged 60 years or more; **OR**
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; **OR**
- Patient must have a family history of coronary heart disease in one or more first degree relatives before the age of 45 years; **OR**
- Patient must have heterozygous familial hypercholesterolaemia; **OR**
- Patient must have homozygous familial hypercholesterolaemia; **OR**
- Patient must have a level of absolute risk of a cardiovascular event greater than 15% over 5 years as calculated using the Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance), as in force on 1 April 2018.

Inadequate control with a statin is defined as a LDL cholesterol concentration in excess of current target lipid levels for primary and secondary prevention after at least 3 months of treatment at a maximum tolerated dose of a statin.

The dose and duration of statin treatment and the cholesterol concentration which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated.
The cholesterol concentration which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

### EZETIMIBE + ATORVASTATIN

#### Note

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**Note**

The Australian Absolute Cardiovascular Disease Risk Calculator is available at www.cvdcheck.org.au

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</table>

Hypercholesterolaemia

**Clinical criteria:**

- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must have cholesterol concentrations that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
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- Patient must have peripheral vascular disease; **OR**
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Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

The type and severity of the adverse event or contraindication must be documented in the patient's medical records.

### EZETIMIBE + SIMVASTATIN

#### Note

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**Authority required (STREAMLINED)**

**7957**

Hypercholesterolaemia

**Clinical criteria:**

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- Patient must have cerebrovascular disease; **OR**
- Patient must have peripheral vascular disease; **OR**
- Patient must have diabetes mellitus with microalbuminuria; **OR**
- Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; **OR**
- Patient must have diabetes mellitus and be aged 60 years or more; **OR**
- Patient must have a family history of coronary heart disease in two or more first degree relatives before the age of 55 years; **OR**
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Microalbuminuria is defined as urinary albumin excretion rate of greater than 20mcg/min or urinary albumin to creatinine ratio of greater than 2.5 for males, or greater than 3.5 for females.

**Ezetimibe 10 mg + Simvastatin 40 mg tablet, 30**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>APO-Ezetimibe/Simvastatin 10/40 [TX]</td>
<td>EZETIMIBE/SIMVASTATIN SANDOZ [SZ]</td>
</tr>
<tr>
<td>EZETORIN [RW]</td>
<td>EzSimva GH 10/40 [GQ]</td>
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<tr>
<td>Pharmacor Ezetimibe Simvastatin 10/40 [CR]</td>
<td>Vytorin [AL]</td>
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<tr>
<td>Zeklen 10/40 mg [AF]</td>
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</tr>
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</table>

**Ezetimibe 10 mg + Simvastatin 80 mg tablet, 30**

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<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>APO-Ezetimibe/Simvastatin 10/80 [TX]</td>
<td>EZETIMIBE/SIMVASTATIN SANDOZ [SZ]</td>
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<tr>
<td>EZETORIN [RW]</td>
<td>EzSimva GH 10/80 [GQ]</td>
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<td>Pharmacor Ezetimibe Simvastatin 10/80 [CR]</td>
<td>Vytorin [AL]</td>
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<td>Zeklen 10/80 mg [AF]</td>
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</table>

**EZETIMIBE + SIMVASTATIN**

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**Authority required (STREAMLINED)**

**7958**

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- Patient must have cerebrovascular disease; **OR**
- Patient must have peripheral vascular disease; **OR**
- Patient must have diabetes mellitus with microalbuminuria; **OR**
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The type and severity of the adverse event or contraindication must be documented in the patient's medical record.

### ezetimibe 10 mg + simvastatin

**Table 1: Ezetimibe 10 mg + Simvastatin 10 mg Tablet, 30**

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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>
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<tbody>
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<td>26.80</td>
<td>28.09</td>
<td>* APO-Ezetimibe/Simvastatin 10/10 [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* EZETORIN [RW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Pharmacor Ezetimibe Simvastatin 10/10 [CR]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Zeklen 10/10 mg [AF]</td>
</tr>
</tbody>
</table>

**Table 2: Ezetimibe 10 mg + Simvastatin 20 mg Tablet, 30**

<table>
<thead>
<tr>
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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>
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<td>27.31</td>
<td>28.60</td>
<td>* APO-Ezetimibe/Simvastatin 10/20 [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* EZETORIN [RW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Pharmacor Ezetimibe Simvastatin 10/20 [CR]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Zeklen 10/20 mg [AF]</td>
</tr>
</tbody>
</table>

**HMG CoA reductase inhibitors, other combinations**

### AMLODIPINE + ATORVASTATIN

**Table 3: Amlodipine 10 mg + Atorvastatin 10 mg Tablet, 30**

<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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<tr>
<td>1</td>
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<td>15.13</td>
<td>16.42</td>
<td>* Cadivast 10/10 [AF]</td>
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<td></td>
<td>15.00</td>
<td>16.32</td>
<td>* Caduet 10/10 [UJ]</td>
</tr>
</tbody>
</table>

**Table 4: Amlodipine 10 mg + Atorvastatin 20 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>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>15.86</td>
<td>17.15</td>
<td>* Cadivast 10/20 [AF]</td>
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<td></td>
<td>15.00</td>
<td>16.60</td>
<td>* Caduet 10/20 [UJ]</td>
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</table>

**Table 5: Amlodipine 10 mg + Atorvastatin 40 mg Tablet, 30**

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<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>
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<td>16.77</td>
<td>18.06</td>
<td>* Cadivast 10/40 [AF]</td>
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<td></td>
<td>15.00</td>
<td>17.15</td>
<td>* Caduet 10/40 [UJ]</td>
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</table>

**Table 6: Amlodipine 10 mg + Atorvastatin 80 mg Tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>18.14</td>
<td>19.43</td>
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<td>15.00</td>
<td>19.43</td>
<td>* Caduet 10/80 [UJ]</td>
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</table>

**Table 7: Amlodipine 5 mg + Atorvastatin 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>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>14.44</td>
<td>15.73</td>
<td>Cadivast 5/10 [AF]</td>
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**Table 8: Amlodipine 5 mg + Atorvastatin 20 mg Tablet, 30**

<table>
<thead>
<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>1</td>
<td>5</td>
<td>..</td>
<td>15.17</td>
<td>16.46</td>
<td>Cadivast 5/20 [AF]</td>
</tr>
</tbody>
</table>
amldipine 5 mg + atorvastatin 40 mg tablet, 30
9051J

<table>
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<tr>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>16.08</td>
<td>17.37</td>
<td>* Cadivast 5/40 [AF]</td>
</tr>
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</table>

amldipine 5 mg + atorvastatin 80 mg tablet, 30
9052K

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRSN $</th>
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<td>1</td>
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<td>..</td>
<td>17.45</td>
<td>18.74</td>
<td>* Cadivast 5/80 [AF]</td>
</tr>
</tbody>
</table>

**DERMATOLOGICALS**

**ANTIFUNGALS FOR DERMATOLOGICAL USE**

**ANTIFUNGALS FOR TOPICAL USE**

*Imidazole and triazole derivatives*

**KETOCONAZOLE**

*Authority required (STREAMLINED) 6434*

Fungal or yeast infection

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

**ketoconazole 2% shampoo, 60 mL**
1574W

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ $</th>
<th>MRSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>‡1</td>
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<td>20.99</td>
<td>22.28</td>
<td>Nizoral 2% [JT]</td>
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</table>

**ketoconazole 2% cream, 30 g**
9024Y

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
<th>MRSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>26.56</td>
<td>27.85</td>
<td>Nizoral 2% Cream [JT]</td>
</tr>
</tbody>
</table>

**MICONAZOLE**

*Authority required (STREAMLINED) 6434*

Fungal or yeast infection

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

**miconazole nitrate 2% cream, 30 g**
9027D

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>MRSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
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<td>..</td>
<td>19.52</td>
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<td>Daktarin [JT]</td>
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**miconazole nitrate 2% cream, 70 g**
9028E

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<th>MRSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>21.20</td>
<td>22.49</td>
<td>Daktarin [JT]</td>
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</tbody>
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**miconazole nitrate 2% powder, 30 g**
9029F

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<th>MRSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>20.25</td>
<td>21.54</td>
<td>Daktarin [JT]</td>
</tr>
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**miconazole 2% solution, 30 mL**
9031H

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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>23.49</td>
<td>24.78</td>
<td>Daktarin Tincture [JT]</td>
</tr>
</tbody>
</table>

**Other antifungals for topical use**

**TERBINAFINE**

*Authority required (STREAMLINED) 6434*

Fungal or yeast infection

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

*Authority required (STREAMLINED) 6412*

Fungal or yeast infection

**Clinical criteria:**
- The condition must be fungal; OR
- The condition must be due to yeast.

**Population criteria:**
• Patient must be 18 years of age or less.

**Terbinafine hydrochloride 1% cream, 15 g**

<table>
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<tr>
<th>Max Qty Packs</th>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>2</td>
<td>3</td>
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<td>38.92</td>
<td>40.21</td>
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</tbody>
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### Antifungals for systemic use

#### GRISEOFULVIN

**Grisofulvin 500 mg tablet, 28**

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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>1</td>
<td>2</td>
<td>..</td>
<td>26.56</td>
<td>27.85</td>
<td>Grisovin 500 [AS]</td>
</tr>
</tbody>
</table>

**Grisofulvin 125 mg tablet, 100**

<table>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>25.75</td>
<td>27.04</td>
<td>Grisovin [AS]</td>
</tr>
</tbody>
</table>

#### TERBINAFINE

**Authority required**

Dermatophyte infection

**Clinical criteria:**

• Patient must have failed to respond to topical treatment.

**Population criteria:**

• Patient must be an Aboriginal or a Torres Strait Islander person.

**Authority required**

Dermatophyte infection

**Clinical criteria:**

• Patient must have failed to respond to topical treatment, AND

• Patient must have failed to respond to griseofulvin.

**Population criteria:**

• Patient must be 18 years of age or less.

**Terbinafine 250 mg tablet, 42**

<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>30.93</td>
<td>32.22</td>
<td>* APO-Terbinfine [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* NOUMED TERBINAFINE [VO]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Terbinafine AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Terbinafine Sandoz [SZ]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* APO-Terbinfine [TX]</td>
</tr>
</tbody>
</table>

#### TERBINAFINE

**Note**

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

**Note**

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

**Authority required**

Onychomycosis

**Clinical criteria:**

• The condition must be proximal or extensive (greater than 80% nail involvement), AND

• Patient must have failed to respond to topical treatment, AND

• The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider; OR

• The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.

The date of the pathology report must be provided at the time of application and must not be more than 12 months old.

**Terbinafine 250 mg tablet, 42**

<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>1</td>
<td>1</td>
<td>..</td>
<td>30.93</td>
<td>32.22</td>
<td>* APO-Terbinfine [TX]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td>* NOUMED TERBINAFINE [VO]</td>
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<td></td>
<td></td>
<td></td>
<td>* Terbinafine AN [EA]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Terbinafine Sandoz [SZ]</td>
</tr>
</tbody>
</table>

### Antipsoriatrics

#### Antipsoriatrics for topical use

Other antipsoriatrics for topical use
- **CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE**

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

  **Authority required (STREAMLINED)**
  7947
  Chronic stable plaque type psoriasis vulgaris

  **Clinical criteria:**
  - The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

  **calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 60 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>64.04</td>
<td>41.00</td>
<td>Daivobet 50/500 gel [LO]</td>
</tr>
</tbody>
</table>

- **CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE**

  **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.

  **Restricted benefit**
  Chronic stable plaque type psoriasis vulgaris

  **Clinical criteria:**
  - The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

  **calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g**

<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>38.03</td>
<td>39.32</td>
<td>* Calcipotriol/Betamethasone Sandoz 50/500 [SZ], * Daivobet [LO]</td>
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</table>

  **calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% foam, 60 g**

<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>84.26</td>
<td>41.00</td>
<td>Enstilar [LO]</td>
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</tbody>
</table>

- **ANTIPSORIATICS FOR SYSTEMIC USE**

  **Retinoids for treatment of psoriasis**

  **ACITRETIN**

  **Caution** This drug is a potent teratogen - pregnancy should be avoided during therapy and for at least three years after cessation of therapy.

  **Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

  **Authority required (STREAMLINED)**
  5789
  Severe intractable psoriasis

  **Authority required (STREAMLINED)**
  5727
  Severe disorders of keratinisation

  **acitretin 10 mg capsule, 100**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<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>2</td>
<td>..</td>
<td>108.27</td>
<td>41.00</td>
<td>* Neotigason [TB], * ZETIN [RW], * Novatin [TX]</td>
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  **acitretin 25 mg capsule, 100**

<table>
<thead>
<tr>
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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>2</td>
<td>..</td>
<td>212.55</td>
<td>41.00</td>
<td>* Neotigason [TB], * ZETIN [RW], * Novatin [TX]</td>
</tr>
</tbody>
</table>

- **SILVER SULFADIAZINE**

  **Restricted benefit**
  Infection
  Treatment Phase: Prevention and treatment

  **Clinical criteria:**
  - The condition must be in partial or full skin thickness loss due to burns; OR

- **CHEMOTHERAPEUTICS FOR TOPICAL USE**

  **Sulfonamides**

- **ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE**
- The condition must be in partial or full skin thickness loss due to epidermolysis bullosa.

**Restricted benefit**

Stasis ulcers

<table>
<thead>
<tr>
<th>silver sulfadiazine 1% cream, 50 g</th>
<th>9479X</th>
<th>Max Qty</th>
<th>Packs</th>
<th>No of Rpts</th>
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<th>DPMQ $</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>21.49</td>
<td>22.78</td>
<td></td>
<td>Flamazine [SN]</td>
</tr>
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</table>

### CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

### CORTICOSTEROIDS, PLAIN

#### HYDROCORTISONE ACETATE

<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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<tbody>
<tr>
<td></td>
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<td>1</td>
<td>..</td>
<td>..</td>
<td>13.88</td>
<td>15.17</td>
<td>*</td>
<td>Cortic-DS 1% [LN]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>* Sigmacort [AS]</td>
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<table>
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<tr>
<td></td>
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<td>1</td>
<td>..</td>
<td>..</td>
<td>13.88</td>
<td>15.17</td>
<td>*</td>
<td>Cortic-DS 1% [LN]</td>
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### HYDROCORTISONE ACETATE

<table>
<thead>
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<th>DPMQ $</th>
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<td>15.17</td>
<td>*</td>
<td>Cortic-DS 1% [LN]</td>
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<td>* Sigmacort [AS]</td>
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<table>
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<th>hydrocortisone acetate 1% ointment, 50 g</th>
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<th>No of Rpts</th>
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<th>DPMQ $</th>
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<td>Cortic-DS 1% [LN]</td>
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<td></td>
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<td></td>
<td></td>
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<td>* Sigmacort [AS]</td>
</tr>
</tbody>
</table>

Corticosteroids, moderately potent (group II)

#### TRIAMCINOLON

<table>
<thead>
<tr>
<th>triamcinolone acetonide 0.02% cream, 100 g</th>
<th>2117K</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></td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*18.96</td>
<td>20.25</td>
<td>* Tricortone [LN]</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Aristocort 0.02% [AS]</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>triamcinolone acetonide 0.02% ointment, 100 g</th>
<th>2118L</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></td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*18.96</td>
<td>20.25</td>
<td>* Tricortone [LN]</td>
<td></td>
<td></td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Aristocort 0.02% [AS]</td>
</tr>
</tbody>
</table>

Corticosteroids, potent (group III)

#### BETAMETHASONE DIPROPIONATE

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>betamethasone (as dipropionate) 0.05% cream, 15 g</th>
<th>1115Q</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></td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>17.86</td>
<td>19.15</td>
<td>* Eleuphrat [OV]</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Diprosone [OQ]</td>
</tr>
</tbody>
</table>
### BETAMETHASONE DIPROPIONATE

**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.

**Clinical criteria:**
- The condition must cover 10-20% of the patient's body surface area.

### betamethasone (as propionate) 0.05% cream, 15 g

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</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>23.70</td>
<td>24.99</td>
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<td>Eleuphrat [OV]</td>
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<tr>
<td></td>
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<td>4.90</td>
<td>28.60</td>
<td>24.99</td>
<td>Diprosone [OQ]</td>
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### betamethasone (as propionate) 0.05% ointment, 15 g

<table>
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<tr>
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<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</tbody>
</table>

### BETAMETHASONE DIPROPIONATE

**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.

**Clinical criteria:**
- The condition must cover 20-40% of the patient's body surface area.

### betamethasone (as propionate) 0.05% cream, 15 g

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</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>4</td>
<td>5</td>
<td></td>
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<td>36.67</td>
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<td>Eleuphrat [OV]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>9.80</td>
<td>45.18</td>
<td>36.67</td>
<td>Diprosone [OQ]</td>
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### betamethasone (as propionate) 0.05% ointment, 15 g

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<td></td>
<td></td>
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<td>45.18</td>
<td>36.67</td>
<td>Diprosone [OQ]</td>
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</tbody>
</table>

### BETAMETHASONE DIPROPIONATE

**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.

**Clinical criteria:**
- The condition must cover 40-60% of the patient's body surface area.

### betamethasone (as propionate) 0.05% cream, 15 g

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</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>
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<tr>
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<td>14.70</td>
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### betamethasone (as propionate) 0.05% ointment, 15 g

<table>
<thead>
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<th>Max Qty</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
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<td>47.04</td>
<td>41.00</td>
<td></td>
<td>Eleuphrat [OV]</td>
</tr>
<tr>
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<td>41.00</td>
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### BETAMETHASONE DIPROPIONATE

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patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
6263
Corticosteroid-responsive dermatoses
Clinical criteria:
- The condition must cover 60-80% of the patient’s body surface area.

betamethasone (as propionate) 0.05% cream, 15 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td></td>
<td></td>
<td></td>
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<td>*78.38</td>
<td>* Diprosone [OQ]</td>
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betamethasone (as propionate) 0.05% ointment, 15 g

<table>
<thead>
<tr>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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<td></td>
<td></td>
<td>19.60</td>
<td>*78.38</td>
<td>* Diprosone [OQ]</td>
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**BETAMETHASONE DIPROPIONATE**

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Authority required (STREAMLINED)
6231
Corticosteroid-responsive dermatoses
Clinical criteria:
- The condition must cover >80% of the patient’s body surface area.

betamethasone (as propionate) 0.05% cream, 15 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tr>
<td></td>
<td></td>
<td></td>
<td>24.50</td>
<td>*94.94</td>
<td>* Diprosone [OQ]</td>
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</table>

betamethasone (as propionate) 0.05% ointment, 15 g

<table>
<thead>
<tr>
<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></td>
<td></td>
<td></td>
<td>24.50</td>
<td>*94.94</td>
<td>* Diprosone [OQ]</td>
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**BETAMETHASONE VALERATE**

Restricted benefit
Corticosteroid-responsive dermatoses

betamethasone (as valerate) 0.02% cream, 100 g

<table>
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<td></td>
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<td>*33.48</td>
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**BETAMETHASONE VALERATE**

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.

Restricted benefit
Corticosteroid-responsive dermatoses

betamethasone (as valerate) 0.05% cream, 15 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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**BETAMETHASONE VALERATE**

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Authority required (STREAMLINED)
6232
Corticosteroid-responsive dermatoses
**Clinical criteria:**
- The condition must cover 10-20% of the patient's body surface area.

**BETAMETHASONE VALERATE**

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

**Authority required (STREAMLINED)**

**6246**
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 20-40% of the patient's body surface area.

<table>
<thead>
<tr>
<th>betamethasone (as valerate) 0.05% cream, 15 g</th>
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**BETAMETHASONE VALERATE**

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</tr>
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</table>

**Authority required (STREAMLINED)**

**6218**
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 40-60% of the patient's body surface area.

<table>
<thead>
<tr>
<th>betamethasone (as valerate) 0.05% cream, 15 g</th>
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<tbody>
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<td>10808W</td>
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**BETAMETHASONE VALERATE**

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

**Authority required (STREAMLINED)**

**6263**
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 60-80% of the patient's body surface area.

<table>
<thead>
<tr>
<th>betamethasone (as valerate) 0.05% cream, 15 g</th>
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</thead>
<tbody>
<tr>
<td>10807T</td>
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**BETAMETHASONE VALERATE**

<table>
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<td>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.</td>
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**Authority required (STREAMLINED)**

**6231**
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover >80% of the patient's body surface area.

<table>
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<tr>
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<tbody>
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## METHYLPREDNISOLONE

**Note Continuing Therapy Only:**
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### Restricted benefit
Corticosteroid-responsive dermatoses

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
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<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advantan [LO]</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Advantan (Fatty) [LO]</td>
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### Authority required (STREAMLINED)

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</thead>
<tbody>
<tr>
<td>6232</td>
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### Clinical criteria:
- The condition must cover 10-20% of the patient’s body surface area.

### Restricted benefit
Eczema

<table>
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<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>Advantan [LO]</td>
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## METHYLPREDNISOLONE

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### Authority required (STREAMLINED)

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### Clinical criteria:
- The condition must cover 10-20% of the patient’s body surface area.
### METHYPREDNISOLONE

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### Authority required (STREAMLINED)

#### 6246
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 20-40% of the patient’s body surface area.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>39.59</td>
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### Authority required (STREAMLINED)

#### 6231
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover >80% of the patient’s body surface area.

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<tr>
<th>Brand Name and Manufacturer</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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### Authority required (STREAMLINED)

#### 6218
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 40-60% of the patient’s body surface area.

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<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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<th>No of Rpts</th>
<th>Premium $</th>
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<td>41.00</td>
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</table>
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**Note** Continuing Therapy Only:

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**Authority required (STREAMLINED)**

6263
Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 60-80% of the patient’s body surface area.

### METHYLpredNISOLONE

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**Authority required (STREAMLINED)**

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Corticosteroid-responsive dermatoses

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- The condition must cover 60-80% of the patient’s body surface area.

### METHYLpredNISOLONE

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**Authority required (STREAMLINED)**

6263
Corticosteroid-responsive dermatoses

**Clinical criteria:**

- The condition must cover 40-60% of the patient’s body surface area.

### MOMETASONE

**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.

**Restricted benefit**

Corticosteroid-responsive dermatoses

### MOMETASONE

**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

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

**Authority required (STREAMLINED)**
6232
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 10-20% of the patient’s body surface area.

<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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### MOMETASONE

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

**Authority required (STREAMLINED)**
6246
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 20-40% of the patient’s body surface area.

<table>
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### MOMETASONE

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

**Authority required (STREAMLINED)**
6218
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 40-60% of the patient’s body surface area.

<table>
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### MOMETASONE

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

**Authority required (STREAMLINED)**
6218
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 40-60% of the patient’s body surface area.
**MOMETASONE**

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

**Authority required (STREAMLINED)**
6263
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 60-80% of the patient’s body surface area.

---

**MOMETASONE**

**Note Continuing Therapy Only:**
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**Authority required (STREAMLINED)**
6231
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover >80% of the patient’s body surface area.

---

**MOMETASONE**

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

**Authority required (STREAMLINED)**
6263
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 60-80% of the patient’s body surface area.
Corticosteroid-responsive dermatoses

**Clinical criteria:**
- The condition must cover 40-60% of the patient’s body surface area.

### mometasone furoate 0.1% lotion, 30 mL

<table>
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*Corticosteroids, very potent (group IV)*

### CLOBETASOL

**Authority required (STREAMLINED)**

**5461**

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

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*Note*

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

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

### ADAPALENE + BENZOYL PEROXIDE

**Restricted benefit**

Severe acne vulgaris

**Clinical criteria:**
- The treatment must be maintenance therapy.

#### adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g

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

### ISOTRETINOIN

**Caution**
This drug causes birth defects.
This drug has been reported to cause other frequent and potentially serious toxicity.

**Note**
Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.
### ISOTRETINOIN

**Caution** This drug causes birth defects.

This drug has been reported to cause other frequent and potentially serious toxicity.

**Note** Pharmaceutical benefits that have form pack size isotretinoin 20 mg capsule, 60 and isotretinoin 20 mg capsule, 30 are equivalent for the purposes of substitution.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Authority required (STREAMLINED)**

5224

Severe cystic acne

**Clinical criteria:**

- The condition must be unresponsive to other therapy.

---

### OTHER DERMATOLOGICAL PREPARATIONS

#### OTHER DERMATOLOGICAL PREPARATIONS

**Agents for dermatitis, excluding corticosteroids**

---

#### PIMECROLIMUS

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

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

**Authority required (STREAMLINED)**

5482

Atopic dermatitis

**Population criteria:**

- Patient must be at least 3 months of age.

**Clinical criteria:**

- The condition must be on the patient's face; OR
- The condition must be on the patient's eyelid. **AND**
- Patient must have 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. **AND**
- Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.

**Authority required (STREAMLINED)**

5472

Atopic dermatitis

Treatment Phase: Short-term (up to 3 weeks) intermittent treatment

---

### Clinical criteria:

- The condition must be unresponsive to other therapy.

### isotretinoin 10 mg capsule, 60

<table>
<thead>
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<td>Isotretinoin Lupin [GQ]</td>
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<tr>
<td>Oratane [RF]</td>
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<td>Dermatane [ER]</td>
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<tr>
<td>Rocta 10 [RW]</td>
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### isotretinoin 40 mg capsule, 30

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<td>Roctana 10 [RW]</td>
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### isotretinoin 30 mg capsule, 60

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### isotretinoin 5 mg capsule, 60

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### Authority required (STREAMLINED)

5224

Severe cystic acne

**Clinical criteria:**

- The condition must be unresponsive to other therapy.

---

### Authority required (STREAMLINED)

5482

Atopic dermatitis

**Population criteria:**

- Patient must be at least 3 months of age.

**Clinical criteria:**

- The condition must be on the patient's face; OR
- The condition must be on the patient's eyelid. **AND**
- Patient must have 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. **AND**
- Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.

**Authority required (STREAMLINED)**

5472

Atopic dermatitis

Treatment Phase: Short-term (up to 3 weeks) intermittent treatment

**Population criteria:**
• Patient must be at least 3 months of age.

**Clinical criteria:**
• The condition must be on the patient's face; OR
• The condition must be on the patient's eyelid, **AND**
• Patient must have failed to achieve satisfactory disease control with intermittent topical corticosteroid therapy, **AND**
• The condition must have been initially diagnosed more than three months prior to this treatment, **AND**
• Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.

*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.*

### Pimecrolimus 1% cream, 15 g

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### Other dermatologicals

#### DAPSONE

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

<table>
<thead>
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### Imiquimod

**Note** The patient or carer must be able to understand and administer the imiquimod dosing regimen.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Treatment of recurrent (previously treated) lesions will not be authorised.
**Note** Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

**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.

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GENITO URINARY SYSTEM AND SEX HORMONES

- GENITO URINARY SYSTEM AND SEX HORMONES
- OTHER GYNECOLOGICALS

CONTRACEPTIVES FOR TOPICAL USE

Intrauterine contraceptives

- LEVONORGESTREL
  Restricted benefit
  Contraception

**levonorgestrel 19.5 mg intrauterine drug delivery system, 1 system**

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<tr>
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- LEVONORGESTREL
  Restricted benefit
  Contraception

**Idiopathic menorrhagia**

Clinical criteria:
- The treatment must be in a patient where oral treatments are ineffective.

**Idiopathic menorrhagia**

Clinical criteria:
- The treatment must be in a patient where oral treatments are contraindicated.

**levonorgestrel 52 mg intrauterine drug delivery system, 1 system**

<table>
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- OTHER GYNECOLOGICALS

Prolactine inhibitors

- BROMOCRIPTINE
  Restricted benefit
  Prevention of the onset of lactation

Clinical criteria:
- The treatment must occur in the puerperium, AND
- The treatment must be for medical reasons.

**bromocriptine 2.5 mg tablet, 30**

<table>
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<th>Max.Qty Packs</th>
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<td>24.18</td>
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<td>Parlodel [SZ]</td>
</tr>
</tbody>
</table>

- BROMOCRIPTINE
  Caution
  Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Restricted benefit
  Acromegaly

Restricted benefit
  Parkinson disease

Restricted benefit
  Pathological hyperprolactinaemia

Clinical criteria:
- Patient must be one in whom surgery is not indicated.

Restricted benefit
  Pathological hyperprolactinaemia

Clinical criteria:
- Patient must have had surgery for this condition with incomplete resolution.

Restricted benefit
  Pathological hyperprolactinaemia

Clinical criteria:
- Patient must be one in whom radiotherapy is not indicated.
bromocriptine 2.5 mg tablet, 30
1443Y

Max Qty Packs No. of Rpts Premium $ DPMO $ MRVS $ Brand Name and Manufacturer
2 5 .. 33.76 35.05 Parloled [SZ]

-**CABERGOLINE**

**Restricted benefit**
Prevention of the onset of lactation

**Clinical criteria:**
- The treatment must occur in the puerperium, **AND**
- The treatment must be for medical reasons.

**cabergoline 500 microgram tablet, 2**
8115D

Max Qty Packs No. of Rpts Premium $ DPMO $ MRVS $ Brand Name and Manufacturer
1 .. .. 25.38 26.67 * APO-Cabergoline [TX] * Dostinex [PF]

-**CABERGOLINE**

**Restricted benefit**
Pathological hyperprolactinaemia

**Clinical criteria:**
- Patient must be one in whom surgery is not indicated.

**cabergoline 500 microgram tablet, 8**
8114C

Max Qty Packs No. of Rpts Premium $ DPMO $ MRVS $ Brand Name and Manufacturer
1 5 .. 65.48 41.00 * APO-Cabergoline [TX] * Dostinex [PF]

-**QUINAGOLIDE**

**Restricted benefit**
Pathological hyperprolactinaemia

**Clinical criteria:**
- Patient must be one in whom surgery is not indicated.

**quinagolide 75 microgram tablet, 30**
8822H

Max Qty Packs No. of Rpts Premium $ DPMO $ MRVS $ Brand Name and Manufacturer
1 5 .. 95.78 41.00 Norprolac [FP]
# GENITO URINARY SYSTEM AND SEX HORMONES

## LEVONORGESTREL + ETHINYLESTRADIOL

| Levonorgestrel 100 microgram + ethinylestradiol 20 microgram tablet [21] (&) inert substance tablet [7], 4 x 28 |
|---|---|---|---|---|---|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1 | 2 | .. | 18.13 | 19.42 | Femme-Tab ED 20/100 [AE] |

| Levonorgestrel 125 microgram + ethinylestradiol 50 microgram tablet [21] (&) inert substance tablet [7], 4 x 28 |
|---|---|---|---|---|---|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1 | 2 | .. | 21.89 | 23.18 | Microgynon 50 ED [BN] |

| Levonorgestrel 150 microgram + ethinylestradiol 30 microgram tablet [21] (&) inert substance tablet [7], 4 x 28 |
|---|---|---|---|---|---|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1 | 2 | .. | 18.13 | 19.42 | Monofeme 28 [FZ] |

## NORETHISTERONE + ETHINYLESTRADIOL

| Norethisterone 500 microgram + ethinylestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28 |
|---|---|---|---|---|---|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1 | 2 | .. | 20.75 | 22.04 | Norimin 28 Day [FZ] |

## PROGESTOGENS AND ESTROGENS, SEQUENTIAL PREPARATIONS

| Norethisterone 1 mg + ethinylestradiol 35 microgram tablet [21] (&) inert substance tablet [7], 4 x 28 |
|---|---|---|---|---|---|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1 | 2 | .. | 9.78 | 10.53 | Brevinor 1 [PF] |

| Norethisterone 1 mg + mestranol 50 microgram tablet [21] (&) inert substance tablet [7], 4 x 28 |
|---|---|---|---|---|---|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1.3 | 2 | .. | 63.84 | 72.09 | Pirmella 1/35 [DZ] |

## ETONOGESTREL

| Etonogestrel 68 mg implant, 1 |
|---|---|---|---|---|---|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1 | .. | .. | 170.35 | 180.00 | Implanon NXT [OQ] |

## LEVONORGESTREL

| Levonorgestrel 30 microgram tablet, 112 tablets [4 x 28] |
|---|---|---|---|---|---|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1 | 2 | .. | 19.72 | 21.01 | Microlut 28 [BN] |
## Medroxyprogesterone

**Medroxyprogesterone acetate 150 mg/mL injection, 1 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>3118D</td>
<td>1</td>
<td>26.15</td>
<td>27.44</td>
<td>a</td>
<td>Depo-Ralovera [FZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7.00</td>
<td>33.15</td>
<td>27.44</td>
<td>a Depo-Provera [PF]</td>
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## Nor ethisterone

**Nor ethisterone 350 microgram tablet, 4 x 28**

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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1967M</td>
<td>2</td>
<td>20.75</td>
<td>22.04</td>
<td></td>
<td>Noriday 28 Day [PF]</td>
</tr>
</tbody>
</table>

## Androgens

### 3-oxoandrostene (4) derivatives

## Testosterone

**Authority required**

Androgen deficiency

**Clinical criteria:**
- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**
- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 aged 40 years or older.

**Treatment criteria:**
- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow 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 under 18 years of age.

**Treatment criteria:**
- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 under 18 years of age.

**Treatment criteria:**
- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 under 18 years of age.

**Treatment criteria:**
Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 5% (50 mg/mL) cream, 50 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>10378F</td>
<td>6</td>
<td>65.76</td>
<td>41.00</td>
<td></td>
<td>AndroForte 5 [LX]</td>
</tr>
</tbody>
</table>

testosterone 1% (50 mg/5 g) gel, 30 x 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>8830R</td>
<td>5</td>
<td>77.52</td>
<td>41.00</td>
<td></td>
<td>Testogel [HB]</td>
</tr>
</tbody>
</table>

testosterone 2.5 mg/24 hours patch, 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>8460G</td>
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<td>78.05</td>
<td>41.00</td>
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<td>Androderm [TB]</td>
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</table>

testosterone 5 mg/24 hours patch, 30

<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>
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<tbody>
<tr>
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<td>78.05</td>
<td>41.00</td>
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<td>Androderm [TB]</td>
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</table>

testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations

<table>
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<tr>
<th>Max Qty Packs</th>
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<tr>
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<td>77.52</td>
<td>41.00</td>
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<td>Testogel [HB]</td>
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</table>

testosterone 2% (23 mg/actuation) gel, 56 actuations

<table>
<thead>
<tr>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>11740X</td>
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<td>82.97</td>
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<td>Testavan [FP]</td>
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</tbody>
</table>

### TESTOSTERONE UNDECANOATE

**Authority required**

**Androgen deficiency**

**Clinical criteria:**
- Patient must have an established pituitary or testicular disorder.

**Treatment criteria:**
- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 aged 40 years or older.

**Treatment criteria:**
- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow 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:
1. Testosterone level of less than 6 nmol per litre; OR
2. 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 under 18 years of age.

**Treatment criteria:**
- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 under 18 years of age.

**Treatment criteria:**
- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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 under 18 years of age.

**Treatment criteria:**
- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow 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.

---

**ESTROGENS**

*Natural and semisynthetic estrogens, plain*

---

**ESTRADIOL**

*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.

---

**estradiol valerate 1 mg tablet, 56**

<table>
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<tr>
<th>Max Qty Packs</th>
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<th>MRVSN ($)</th>
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<tr>
<td>1</td>
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<td>Progynova [BN]</td>
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**estradiol 10 microgram modified release pessary, 18**

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<tr>
<td>1</td>
<td>2</td>
<td>34.09</td>
<td>35.38</td>
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<td>Vagifem Low [NO]</td>
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**estradiol valerate 2 mg tablet, 56**

<table>
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<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1</td>
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<td>18.52</td>
<td>19.81</td>
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<td>Progynova [BN]</td>
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**estradiol 2 mg tablet, 56**

<table>
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<th>Max Qty Packs</th>
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<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
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<td>1</td>
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<td>18.22</td>
<td>19.51</td>
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<td>Zumenon [GO]</td>
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</tbody>
</table>

---

**ESTRADIOL**

*Note Estradiol should be used in conjunction with an oral progestogen in women with an intact uterus.*

*Note Continuing Therapy Only:*

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

---

**estradiol 75 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>
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<tbody>
<tr>
<td>‡1</td>
<td>5</td>
<td>23.07</td>
<td>24.36</td>
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<td>Estradot 75 [SZ]</td>
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**estradiol 100 microgram/24 hours patch, 8**

<table>
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<th>DPMQ ($)</th>
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<th>Brand Name and Manufacturer</th>
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<td>Estraderm MX 100 [JU]</td>
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<td>DPMQ $</td>
<td>MRVSN $</td>
<td>Brand Name and Manufacturer</td>
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<td>$1</td>
<td>5</td>
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<td>23.07</td>
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<table>
<thead>
<tr>
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<tbody>
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<table>
<thead>
<tr>
<th>Estradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets</th>
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<tbody>
<tr>
<td>8286D</td>
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<td>Max Qty Packs</td>
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<thead>
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<table>
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<td>8126Q</td>
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<td>Max Qty Packs</td>
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<table>
<thead>
<tr>
<th>Estradiol 37.5 microgram/24 hours patch, 8</th>
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<td>8762E</td>
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<td>Max Qty Packs</td>
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</table>

### ESTRIOL

**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>
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<th>Estradiol 500 microgram pessary, 15</th>
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<tbody>
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<td>Max Qty Packs</td>
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<tr>
<td>$1</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Estradiol 0.1% (1 mg/g) cream, 15 g</th>
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</thead>
<tbody>
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</tbody>
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### PROGESTOGENS

**Pregnen (4) derivatives**

### MEDROXYPROGESTERONE

**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

General Pharmaceutical Benefits

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>
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<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>18.89</td>
<td>20.18</td>
<td>* Ralovera [FZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6.70</td>
<td>25.59</td>
<td>* Provera [PF]</td>
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</table>

medroxyprogesterone acetate 5 mg tablet, 56

<table>
<thead>
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<tbody>
<tr>
<td>1</td>
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<td>21.31</td>
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<tr>
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<td></td>
<td>6.70</td>
<td>26.72</td>
<td>* Provera [PF]</td>
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</table>

**MEDROXYPROGESTERONE**

Restricted benefit

Endometriosis

medroxyprogesterone acetate 10 mg tablet, 100

<table>
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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
<td></td>
<td></td>
<td></td>
<td>6.70</td>
<td>41.62</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>
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<td>..</td>
<td>34.23</td>
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<td>Primolut N [BN]</td>
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</tbody>
</table>

**PROGESTOGENS AND ESTROGENS IN COMBINATION**

Progestogens and estrogens, fixed combinations

**ESTRADIOL + 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.

estradiol 1 mg + dydrogesterone 5 mg tablet, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>MRVSN $</th>
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<td>5</td>
<td>..</td>
<td>22.75</td>
<td>24.04</td>
<td>Femoston-Conti [GO]</td>
</tr>
</tbody>
</table>

**ESTRADIOL + NORETHISTERONE 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.

estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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<td>5</td>
<td>..</td>
<td>23.07</td>
<td>24.36</td>
<td>Estalis continuous 50/250 [SZ]</td>
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</table>

**ESTRADIOL + NORETHISTERONE 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.

estradiol 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>
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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>23.07</td>
<td>24.36</td>
<td>Estalis continuous 50/140 [SZ]</td>
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</table>

Progestogens and estrogens, sequential preparations

**ESTRADIOL (&) ESTRADIOL + 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.

estradiol 1 mg tablet [14] (&) estradiol 1 mg + dydrogesterone 10 mg tablet [14], 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
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<td>5</td>
<td>..</td>
<td>22.75</td>
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<td>Femoston 1/10 [GO]</td>
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</table>
### Genito Urinary System and Sex Hormones

#### Estradiol 2 mg Tablet [14] (&) Estradiol 2 mg + Dydrogesterone 10 mg Tablet [14], 28

<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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</thead>
<tbody>
<tr>
<td>†1</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td>Femoston 2/10 [GO]</td>
</tr>
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</table>

#### No Retosterone Acetate + Estradiol (&) Estradiol

**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.

#### Estradiol 50 Microgram/24 Hours Patch [4] (&) Estradiol 50 Microgram/24 Hours + Norethisterone Acetate 140 Microgram/24 Hours Patch [4], 8

<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>5</td>
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<td></td>
<td></td>
<td>Estalis sequi 50/140 [SZ]</td>
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</table>

#### Estradiol 50 Microgram/24 Hours Patch [4] (&) Estradiol 50 Microgram/24 Hours + Norethisterone Acetate 250 Microgram/24 Hours Patch [4], 8

<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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</thead>
<tbody>
<tr>
<td>†1</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td>Estalis sequi 50/250 [SZ]</td>
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</tbody>
</table>

### Gonadotropins and Other Ovulation Stimulants

#### Gonadotropins

**Follitropin Alfa**

**Note Biosimilar prescribing policy**
Prescribing of the biosimilar brand, Bemfola, is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

**Note**
Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

**Note**
Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**Restricted benefit**
Anovulatory infertility

**Note**
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.

**Note**
Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

**Clinical criteria:**
- The condition must be due to hypogonadotropic hypogonadism, **AND**
- The treatment must be following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis, **AND**
- The treatment must be administered with human chorionic gonadotrophin.

#### Follitropin Alfa 225 Units (16.5 microgram)/0.375 mL Injection, 5 x 0.375 mL Pen Devices

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
<td>3</td>
<td>1</td>
<td>*1369.89</td>
<td>41.00</td>
<td></td>
<td>Bemfola [FX]</td>
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</tbody>
</table>

#### Follitropin Alfa 75 Units (5.5 microgram)/0.125 mL Injection, 5 x 0.125 mL Pen Devices

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
<td>3</td>
<td>1</td>
<td>*469.17</td>
<td>41.00</td>
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<td>Bemfola [FX]</td>
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</tbody>
</table>

#### Follitropin Alfa 150 Units (11 microgram)/0.25 mL Injection, 5 x 0.25 mL Pen Devices

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
<td>3</td>
<td>1</td>
<td>*931.29</td>
<td>41.00</td>
<td></td>
<td>Bemfola [FX]</td>
</tr>
</tbody>
</table>

#### Follitropin Alfa 300 Units (21.84 microgram)/0.5 mL Injection, 0.5 mL Pen Device

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>*376.74</td>
<td>41.00</td>
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<td>Gonal-f Pen [SG]</td>
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#### Follitropin Alfa 450 Units (32.76 microgram)/0.75 mL Injection, 0.75 mL Pen Device

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>*561.57</td>
<td>41.00</td>
<td></td>
<td>Gonal-f Pen [SG]</td>
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</tbody>
</table>
follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL pen device

<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>871SQ</td>
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<td>5</td>
<td>..</td>
<td>$746.46</td>
<td>Gonal-f Pen [SG]</td>
</tr>
</tbody>
</table>

**FOLLITROPIN BETA**

*Note* Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

*Note* Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**Restricted benefit**

Anovulatory infertility

*Note* 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.

*Note* Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

**HUMAN CHORIONIC GONADOTROPHIN**

*Note* Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

**Restricted benefit**

Anovulatory infertility

*Note* Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.

*Note* 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.

*Note* Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

**Restricted benefit**

Infertility

*Note* The condition must be due to hypogonadotrophic hypogonadism.

*Note* The treatment must be following failure of 6 months' treatment with human chorialogonadotrophin to achieve adequate spermatogenesis.

*Note* The treatment must be administered with human chorionic gonadotrophin.

follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
<tr>
<td>856ST</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>$419.67</td>
<td>Puregon 300 IU/0.36 mL [OQ]</td>
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follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge

<table>
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<tr>
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<tr>
<td>8566W</td>
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<td>5</td>
<td>..</td>
<td>$543.86</td>
<td>Puregon 600 IU/0.72 mL [OQ]</td>
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</table>

follitropin beta 900 units/1.08 mL injection, 1.08 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>8871X</td>
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<td>5</td>
<td>..</td>
<td>$805.08</td>
<td>Puregon 900 IU/1.08 mL [OQ]</td>
</tr>
</tbody>
</table>

**Restricted benefit**

Combined deficiency of human growth hormone and gonadotrophins

**Population criteria:**

- Patient must be male.

**Clinical criteria:**

- The condition must be associated with isolated luteinising hormone deficiency.

**Restricted benefit**

Hypogonadism or delayed puberty

**Population criteria:**

- Patient must be male, AND
**GENITO URINARY SYSTEM AND SEX HORMONES**

**Schedule of Pharmaceutical Benefits – December 2020**

- **Patient must be aged 16 years or older.**
- **Clinical criteria:**
  - Patient must show clinical evidence of the condition, **AND**
  - The treatment must not extend beyond 6 months.

### **human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack**

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No of Rpts</th>
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<td>1148R</td>
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<td>..</td>
<td>45.97</td>
<td>41.00</td>
<td>Pregnyl [OQ]</td>
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</table>

### **Ovulation stimulants, synthetic**

- **CLOMIFENE**

  **Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

- **Restricted benefit**
  - Anovulatory infertility

### **clomifene citrate 50 mg tablet, 10**

<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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<td>1211R</td>
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<td>..</td>
<td>36.45</td>
<td>37.74</td>
<td>Clomid [SW]</td>
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</table>

### **ANTIANDROGENS**

- **Antiandrogens, plain**

#### **CYPROTERONE**

- **cyproterone acetate 100 mg tablet, 50**

<table>
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<th>Max Qty</th>
<th>No of Rpts</th>
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<th>DPMQ $</th>
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<td>67.80</td>
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- **cyproterone acetate 50 mg tablet, 50**

<table>
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<th>DPMQ $</th>
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<td>..</td>
<td>83.62</td>
<td>41.00</td>
<td></td>
</tr>
</tbody>
</table>

#### **CYPROTERONE**

- **Caution** This drug should not be used during pregnancy as it may result in feminisation of the male foetus.
- **Authority required (STREAMLINED)**

### **5532**

Moderate to severe androgenisation

- **Clinical criteria:**
  - The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation.

- **Population criteria:**
  - Patient must be female.

### **cyproterone acetate 50 mg tablet, 20**

<table>
<thead>
<tr>
<th>Max Qty</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>
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<td>5</td>
<td>..</td>
<td>26.34</td>
<td>27.63</td>
<td></td>
</tr>
</tbody>
</table>

- **OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM**

- **Progesterone receptor modulators**
MIFEPRISTONE (&) MISOPROSTOL

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

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

**Authority required**
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.

**OXYBUTYNIN**

**Restricted benefit**
Detrusor overactivity

**Oxybutynin hydrochloride 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>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>8039D</td>
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<td>5</td>
<td>15.83</td>
<td>17.12</td>
<td>* Ditropan [SW]</td>
<td>* Oxybutynin Sandoz [SZ]</td>
</tr>
</tbody>
</table>

**OXYBUTYNIN**

**Restricted benefit**
Detrusor overactivity

**Clinical criteria:**
- Patient must be unable to tolerate oral oxybutynin; OR
- Patient must be unable to 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>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>9454N</td>
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<td>5</td>
<td>37.07</td>
<td>38.36</td>
<td>Oxytrol [TT]</td>
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</table>

**PROPANTHELINE**

**Restricted benefit**
Detrusor overactivity

**Propantheline bromide 15 mg tablet, 100**

<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>1953T</td>
<td>2</td>
<td>5</td>
<td>26.16</td>
<td>27.45</td>
<td>Pro-Banthine [RW]</td>
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</tbody>
</table>

**BICARBONATE**

**sodium bicarbonate 840 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>9470K</td>
<td>1</td>
<td>2</td>
<td>20.21</td>
<td>21.50</td>
<td>Sodibic [AS]</td>
</tr>
</tbody>
</table>

**PHENOXYBENZAMINE**

**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.

**Restricted benefit**
Phaeochromocytoma

**Restricted benefit**
Neurogenic urinary retention

**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>5</td>
<td>963.97</td>
<td>41.00</td>
<td>Dibenyline [GH]</td>
</tr>
</tbody>
</table>
Alpha-adrenoreceptor antagonists

DUTASTERIDE + TAMSOLOSIN

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

Authority required (STREAMLINED)
6189
Benign prostatic hyperplasia
Clinical criteria:
• Patient must have lower urinary tract symptoms, **AND**
• Patient must have moderate to severe benign prostatic hyperplasia.

dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30

Testosterone-5-alpha reductase inhibitors

DUTASTERIDE

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

Authority required (STREAMLINED)
6202
Benign prostatic hyperplasia
Clinical criteria:
• Patient must have lower urinary tract symptoms, **AND**
• Patient must have moderate to severe benign prostatic hyperplasia, **AND**
• The treatment must be in combination with an alpha-antagonist.

dutasteride 500 microgram capsule, 30

 SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

ACTH

TETRACOSACTIDE (TETRACOSACTRIN)

Restricted benefit
Hypsarrhythmia and/or infantile spasms
tetracosactide (tetracosactrin) 1 mg/mL modified release injection, 1 mL ampoule

Thyrotopin

THYROTROPIN ALFA

Restricted benefit
Ablation of thyroid remnant tissue
Clinical criteria:
• Patient must have undergone a thyroidectomy, **AND**
• The treatment must be in combination with radioactive iodine, **AND**
• Patient must not have a known metastatic disease.
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

General Pharmaceutical Benefits

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>thyrotropin alfa 900 microgram injection, 2 vials</td>
<td>Thyrogen [GZ]</td>
</tr>
</tbody>
</table>

POSTERIOR PITUITARY LOBE HORMONES

Vasopressin and analogues

DESMOPRESSIN

Authority required (STREAMLINED) 5266
Cranial diabetes insipidus

desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL

Max. Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>5</td>
<td>..</td>
<td>*127.04</td>
<td>41.00</td>
<td>Minirin [FP]</td>
</tr>
</tbody>
</table>

DESMOPRESSIN acetate 10 microgram/actuation nasal spray, 60 actuations

Max. Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*126.88</td>
<td>41.00</td>
<td>Minirin Nasal Spray [FP]</td>
</tr>
</tbody>
</table>

DESMOPRESSIN acetate 200 microgram tablet, 30

Max. Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*141.54</td>
<td>41.00</td>
<td>Minirin [FP]</td>
</tr>
</tbody>
</table>

DESMOPRESSIN

Note Not to be used in preference to enuresis alarms.

Note Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.

Authority required (STREAMLINED) 5413
Primary nocturnal enuresis

Population criteria:
- Patient must be 6 years of age or older.

Clinical criteria:
- Patient must be refractory to an enuresis alarm.

Authority required (STREAMLINED) 5295
Primary nocturnal enuresis

Population criteria:
- Patient must be 6 years of age or older.

Clinical criteria:
- Patient must be one in whom an enuresis alarm is contraindicated.
The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

desmopressin acetate 200 microgram tablet, 30

Max. Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>54.72</td>
<td>41.00</td>
<td>Minirin [FP]</td>
</tr>
</tbody>
</table>

DESMOPRESSIN

Caution Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

Note Not to be used in preference to enuresis alarms.

Authority required (STREAMLINED) 5342
Primary nocturnal enuresis

Population criteria:
- Patient must be 6 years of age or older.

Clinical criteria:
- Patient must be refractory to an enuresis alarm.

Authority required (STREAMLINED) 5267
Primary nocturnal enuresis

Population criteria:
- Patient must be 6 years of age or older.

Clinical criteria:
- Patient must be one in whom an enuresis alarm is contraindicated.
The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated
**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

### DESMOPRESSIN

Note Not to be used in preference to enuresis alarms.

Note 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.

### Authority required (STREAMLINED)

#### 5412
Primary nocturnal enuresis

**Population criteria:**
- Patient must be 6 years of age or older.

**Clinical criteria:**
- Patient must be refractory to an enuresis alarm.

#### 5226
Primary nocturnal enuresis

**Population criteria:**
- Patient must be 6 years of age or older.

**Clinical criteria:**
- Patient must be one in whom an enuresis alarm is contraindicated. The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated.

### desmopressin 120 microgram sublingual wafer, 30

#### Authority required (STREAMLINED)

#### 5412
Primary nocturnal enuresis

**Population criteria:**
- Patient must be 6 years of age or older.

**Clinical criteria:**
- Patient must be refractory to an enuresis alarm.

#### 5226
Primary nocturnal enuresis

**Population criteria:**
- Patient must be 6 years of age or older.

**Clinical criteria:**
- Patient must be one in whom an enuresis alarm is contraindicated. The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated.

### desmopressin 240 microgram sublingual wafer, 30

#### Authority required (STREAMLINED)

#### 5412
Primary nocturnal enuresis

**Population criteria:**
- Patient must be 6 years of age or older.

**Clinical criteria:**
- Patient must be refractory to an enuresis alarm.

#### 5226
Primary nocturnal enuresis

**Population criteria:**
- Patient must be 6 years of age or older.

**Clinical criteria:**
- Patient must be one in whom an enuresis alarm is contraindicated. The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated.

### HYPOTHALAMIC HORMONES

**Gonadotropin-releasing hormones**

### NAFARELIN

**Restricted benefit**

**Endometriosis**

**Treatment Phase:** Initial treatment, for up to 6 months

**Clinical criteria:**
- The condition must be visually proven.

**Restricted benefit**

**Endometriosis**

**Treatment Phase:** Subsequent treatment, for up to 6 months

**Clinical criteria:**
- The condition must be visually proven, AND
- The treatment must not be within 2 years of the end of the previous course of treatment with this drug, AND
- Patient must have had a recent bone density assessment. The date of the bone density assessment must be recorded in the patient's medical records.

### nafarelin 200 microgram/actuation nasal spray, 60 actuations

#### Authority required (STREAMLINED)

#### 5412
Primary nocturnal enuresis

**Population criteria:**
- Patient must be 6 years of age or older.

**Clinical criteria:**
- Patient must be refractory to an enuresis alarm.

#### 5226
Primary nocturnal enuresis

**Population criteria:**
- Patient must be 6 years of age or older.

**Clinical criteria:**
- Patient must be one in whom an enuresis alarm is contraindicated. The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated.

### 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*
- Local intra-articular or peri-articular infiltration
- Keloid
- Lichen planus hypertrophic

**betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL (total betamethasone 5.7 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>
</thead>
<tbody>
<tr>
<td>5034Y</td>
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<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>28.18</td>
<td>29.47</td>
<td>Celestone Chronodose [OQ]</td>
</tr>
</tbody>
</table>

**BETAMETHASONE ACETATE + BETAMETHASONE 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.

*Restricted benefit*
- Alopecia areata
- Local intra-articular or peri-articular infiltration
- Granulomata

*Clinical criteria:*
- The condition must be dermal.
- Keloid
- Lichen planus hypertrophic
- Lichen simplex chronicus
- Chronic discoid lupus erythematosus
- Necrobiotic lipoidica
- Restricted benefit

**betamethasone acetate 3 mg/mL + betamethasone sodium phosphate 3.9 mg/mL (total betamethasone 5.7 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>
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<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>28.18</td>
<td>29.47</td>
<td>Celestone Chronodose [OQ]</td>
</tr>
</tbody>
</table>

**CORTISONE**

*Note Continuation Therapy Only:*
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing 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>
<tr>
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<td>1</td>
<td>4</td>
<td>..</td>
<td>24.48</td>
<td>25.77</td>
<td>Cortate [AS]</td>
</tr>
</tbody>
</table>

**cortisone acetate 5 mg tablet, 50**

<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>
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<tr>
<td>1</td>
<td>4</td>
<td>..</td>
<td>19.35</td>
<td>20.64</td>
<td>Cortate [AS]</td>
</tr>
</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.
practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

dexamethasone 4 mg tablet, 30
2507Y

<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></td>
<td>1</td>
<td>4</td>
<td>17.22</td>
<td>18.51</td>
<td>Dexamethone [AS]</td>
</tr>
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</table>

dexamethasone 500 microgram tablet, 30
1292B

<table>
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<th>Max Qty Packs</th>
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<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td></td>
<td>1</td>
<td>4</td>
<td>14.12</td>
<td>15.41</td>
<td>Dexamethone [AS]</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
1500Y

<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></td>
<td>1</td>
<td>4</td>
<td>32.66</td>
<td>33.95</td>
<td>* Hydrocortisone Mylan 20 [AL]</td>
</tr>
</tbody>
</table>

hydrocortisone 4 mg tablet, 50
1499X

<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></td>
<td>1</td>
<td>4</td>
<td>26.48</td>
<td>27.77</td>
<td>* Hydrocortisone Mylan 4 [AL]</td>
</tr>
</tbody>
</table>

**HYDROCORTISONE SODIUM SUCCINATE**

hydrocortisone (as sodium succinate) 100 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial
1501B

<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></td>
<td>2</td>
<td></td>
<td>*21.82</td>
<td>23.11</td>
<td>Solu-Cortef [PF]</td>
</tr>
</tbody>
</table>

hydrocortisone (as sodium succinate) 250 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial
3096Y

<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></td>
<td>1</td>
<td></td>
<td>20.78</td>
<td>22.07</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 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial
1510L

<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></td>
<td>6</td>
<td></td>
<td>*41.40</td>
<td>41.00</td>
<td>Solu-Cortef [PF]</td>
</tr>
</tbody>
</table>

hydrocortisone (as sodium succinate) 250 mg injection [1 chamber] (&) inert substance diluent [2 mL chamber], 1 dual chamber vial
5118J

<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></td>
<td>6</td>
<td></td>
<td>*64.56</td>
<td>41.00</td>
<td>Solu-Cortef [PF]</td>
</tr>
</tbody>
</table>

**METHYLPREDNISOLONE**

methylprednisolone 1 g injection, 1 vial
5264C

<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></td>
<td>1</td>
<td></td>
<td>44.52</td>
<td>41.00</td>
<td>* Methylpred [AL]</td>
</tr>
</tbody>
</table>

methylprednisolone 1 g injection, 1 vial

<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></td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>* Methylprednisolone Alphapharm [AF]</td>
</tr>
</tbody>
</table>
## METHYLPREDNISOLONE

**Restricted benefit**

Local intra-articular or peri-articular infiltration

**methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Depo-Nisolone [FZ]</em></td>
<td>23.40</td>
<td>24.69</td>
<td></td>
</tr>
<tr>
<td><em>Depo-Medrol [PF]</em></td>
<td>26.01</td>
<td>24.69</td>
<td></td>
</tr>
</tbody>
</table>

**methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Depo-Nisolone [FZ]</em></td>
<td>23.40</td>
<td>24.69</td>
<td></td>
</tr>
<tr>
<td><em>Depo-Medrol [PF]</em></td>
<td>26.01</td>
<td>24.69</td>
<td></td>
</tr>
</tbody>
</table>

**METHYLPREDNISOLONE**

Note: Pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) with diluent are equivalent for the purposes of substitution.

**methylprednisolone 40 mg injection, 5 vials**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Predsolone [LN]</em></td>
<td>14.58</td>
<td>15.87</td>
<td></td>
</tr>
<tr>
<td><em>Panafcortelone [AS]</em></td>
<td>15.58</td>
<td>15.87</td>
<td></td>
</tr>
</tbody>
</table>

**PREDNISOLONE**

**prednisolone 1 mg tablet, 100**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Predosone [LN]</em></td>
<td>14.53</td>
<td>15.82</td>
<td></td>
</tr>
<tr>
<td><em>Panafcort [AS]</em></td>
<td>15.53</td>
<td>15.82</td>
<td></td>
</tr>
</tbody>
</table>

**prednisolone 25 mg tablet, 30**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>PredMix [LN]</em></td>
<td>19.22</td>
<td>20.51</td>
<td></td>
</tr>
<tr>
<td><em>Redipred [AS]</em></td>
<td>21.57</td>
<td>20.51</td>
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**prednisolone 5 mg tablet, 60**

<table>
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<tbody>
<tr>
<td><em>PredMix [LN]</em></td>
<td>19.22</td>
<td>20.51</td>
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<tr>
<td><em>Redipred [AS]</em></td>
<td>21.57</td>
<td>20.51</td>
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</tbody>
</table>

**PREDNISOLONE SODIUM PHOSPHATE**

**prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td><em>Predsone [LN]</em></td>
<td>14.53</td>
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<tr>
<td><em>Panafcort [AS]</em></td>
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**PREDNISONE**

**prednisone 1 mg tablet, 100**

<table>
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<tbody>
<tr>
<td><em>Predsone [LN]</em></td>
<td>14.53</td>
<td>15.82</td>
<td></td>
</tr>
<tr>
<td><em>Panafcort [AS]</em></td>
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**prednisone 25 mg tablet, 30**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium ($)</th>
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<th>MRVSN ($)</th>
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</thead>
<tbody>
<tr>
<td><em>Predsone [LN]</em></td>
<td>14.53</td>
<td>15.82</td>
<td></td>
</tr>
<tr>
<td><em>Panafcort [AS]</em></td>
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**prednisone 5 mg tablet, 60**

<table>
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<th>Premium ($)</th>
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<tbody>
<tr>
<td><em>Predsone [LN]</em></td>
<td>14.53</td>
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<tr>
<td><em>Panafcort [AS]</em></td>
<td>15.53</td>
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## TRIAMCINOLONE

**Restricted benefit**

Local intra-articular or peri-articular infiltration
Restricted benefit
Keloid

Restricted benefit
Lichen planus hypertrophic

TRIAMCINOLONE

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.

Restricted benefit
Alopecia areata

Restricted benefit
Local intra-articular or peri-articular infiltration

Restricted benefit
Granulomata

Clinical criteria:
• The condition must be dermal.

Restricted benefit
Keloid

Restricted benefit
Lichen planus hypertrophic

Restricted benefit
Lichen simplex chronicus

Restricted benefit
Chronic discoid lupus erythematosus

Restricted benefit
Necrobiosis lipoidica

Restricted benefit
Psoriasis

Triamcinolone acetonide 10 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>DPMO $</th>
<th>MRVSN $</th>
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<tr>
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<td>28.18</td>
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THYROID THERAPY

THYROID PREPARATIONS

Thyroid hormones

LEVOTHYROXINE

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.

Levothyroxine sodium 100 microgram tablet, 200

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMO $</th>
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<tbody>
<tr>
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<td>1</td>
<td>27.29</td>
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<td>a Eutroxsig [LN]</td>
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Levothyroxine sodium 200 microgram tablet, 200

<table>
<thead>
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<th>MRVSN $</th>
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Levothyroxine sodium 50 microgram tablet, 200

<table>
<thead>
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<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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<tbody>
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Levothyroxine sodium 75 microgram tablet, 200

<table>
<thead>
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<tbody>
<tr>
<td>1</td>
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<td>27.32</td>
<td>28.61</td>
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</table>
### LIOTHYRONINE

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

| Authority required (STREAMLINDED) 6382 Thyroid cancer Authority required (STREAMLINDED) 6410 Hypothyroidism Clinical criteria: | • The treatment must be for replacement therapy, **AND** • Patient must have documented intolerance to levothyroxine sodium; **OR** • Patient must have documented resistance to levothyroxine sodium. Authority required (STREAMLINDED) 6475 Hypothyroidism Clinical criteria: | • The condition must be severe hypothyroidism, **AND** • The treatment must be for initiation of therapy only.

**liothyronine sodium 20 microgram tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
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<tr>
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<td>41.00</td>
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### ANTITHYROID PREPARATIONS

#### Thiouracils

**propylthiouracil 50 mg tablet, 100**

<table>
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<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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<tr>
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<td>43.48</td>
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<td>PTU [FF]</td>
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</table>

**Sulfur-containing imidazole derivatives**

#### CARBIMAZOLE

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

**carbimazole 5 mg tablet, 100**

<table>
<thead>
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<th>Brand Name and Manufacturer</th>
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<tr>
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<td>40.89</td>
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<td>* Neo-Mercazol [GH]</td>
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<tr>
<td></td>
<td></td>
<td>*39.60</td>
<td>40.89</td>
<td></td>
<td>* NeoMerkazol [BZ]</td>
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</tbody>
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### PANCREATIC HORMONES

#### GLYCOGENOLYTIC HORMONES

**Glycogenolytic hormones**

**glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 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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<tbody>
<tr>
<td>1449G</td>
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<td>49.66</td>
<td>41.00</td>
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<td>GlucaGen Hypokit [NO]</td>
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</tbody>
</table>

**glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 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>5105Q</td>
<td>1</td>
<td>49.66</td>
<td>41.00</td>
<td></td>
<td>GlucaGen Hypokit [NO]</td>
</tr>
</tbody>
</table>
CALCIUM HOMEOSTASIS

PARATHYROID HORMONES AND ANALOGUES

TERIPARATIDE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Severe established osteoporosis
Treatment Phase: Initial treatment

Treatment criteria:
- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

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.

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 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.

TERIPARATIDE 250 microgram/mL injection, 2.4 mL pen device

<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>Forteo [LY]</td>
<td>378.65</td>
<td>41.00</td>
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</tr>
</tbody>
</table>

ANTI-PARATHYROID AGENTS

CALCITONIN SALMON (SALCATONIN)

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.

Restricted benefit
Symptomatic Paget disease of bone

Restricted benefit
Hypercalcaemia

Clinical criteria:
• The treatment must be initiated in a hospital.

calcitonin salmon (salcatonin) 100 units/mL injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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<tr>
<td>2997R</td>
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<td></td>
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<td></td>
<td>Miocalcic 100 [EU]</td>
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Other anti-parathyroid agents

CINACALCET

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.

Authority required (STREAMLINED)

10068
Secondary hyperparathyroidism
Treatment Phase: Continuing treatment
Clinical criteria:
• Patient must have chronic kidney disease, AND
• Patient must be on dialysis, AND
• Patient must have achieved a decrease of at least 30% in intact parathyroid hormone (iPTH) concentrations after 6 months treatment; OR
• Patient must have an intact parathyroid (iPTH) concentration greater than 15 pmol/L and an (adjusted) serum calcium concentration of less than 2.6 mmol/L after 6 months.
During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.
During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient’s response and tolerability.

cinacalcet 60 mg tablet, 28

<table>
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<tr>
<th>Max Qty Packs</th>
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<tbody>
<tr>
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 cinacalcet 90 mg tablet, 28

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 cinacalcet 30 mg tablet, 28

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ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

TETRACYCLINES

Tetracyclines

DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

doxycycline 100 mg tablet, 7

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>Doxycycline Sandoz [HX]</td>
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 doxycycline 100 mg tablet, 7

<table>
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 doxycycline 100 mg tablet, 7

<table>
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 doxycycline 100 mg tablet, 7

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<td></td>
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<td>Doxycycline Sandoz [HX]</td>
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</table>
antiinfectives for systemic use

**Schedule of Pharmaceutical Benefits – December 2020**

### General

**DOXYCYCLINE**

Note: Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

#### Restricted benefit

**Urethritis**

**DOXYCYCLINE**

Note: Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

#### Restricted benefit

**Severe acne**

**Pelvic inflammatory disease**

### Antimicrobial Agents

#### 1. Doxycycline

**Doxycycline 100 mg modified release capsule, 7**

<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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<tr>
<td>1</td>
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<td>2.96</td>
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**Doxycycline 100 mg modified release capsule, 7**

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<td>Mayne Pharma Doxycycline [YT]</td>
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<td>2.96</td>
<td>16.44</td>
<td>14.77</td>
<td>Doryx [YN]</td>
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**Doxycycline 100 mg tablet, 7**

<table>
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<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<td>3</td>
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<td>*16.41</td>
<td>17.70</td>
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<td>Doxycycline AN [EA]</td>
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<tr>
<td>3</td>
<td></td>
<td>*16.41</td>
<td>17.70</td>
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<td>Doxylin 100 [AF]</td>
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**Doxycycline 100 mg tablet, 7**

<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>3</td>
<td></td>
<td>*16.41</td>
<td>17.70</td>
<td></td>
<td>Doxycycline Sandoz [HX]</td>
</tr>
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</table>

**Doxycycline 100 mg tablet, 21**

<table>
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<tr>
<th>Max Qty Packs</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td></td>
<td>16.41</td>
<td>17.70</td>
<td></td>
<td>Doxycycline AN [EA]</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>16.41</td>
<td>17.70</td>
<td></td>
<td>Doxylin 100 [AF]</td>
</tr>
</tbody>
</table>

**Doxycycline 100 mg tablet, 21**

<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>16.41</td>
<td>17.70</td>
<td></td>
<td>APO-Doxycycline [TX]</td>
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</table>

**Doxycycline 100 mg modified release capsule, 21**

<table>
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<th>Max Qty Packs</th>
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<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td></td>
<td>3.21</td>
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<td>17.70</td>
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</tr>
<tr>
<td>1</td>
<td></td>
<td>9.00</td>
<td>25.41</td>
<td>17.70</td>
<td>Doryx [YN]</td>
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**Doxycycline 100 mg modified release capsule, 21**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4</td>
<td>5</td>
<td>*17.86</td>
<td>19.15</td>
<td></td>
<td>Doxylin 100 [AF]</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>*17.86</td>
<td>19.15</td>
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**Doxycycline 100 mg modified release capsule, 7**

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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>5</td>
<td>*6.16</td>
<td>*24.02</td>
<td>19.15</td>
<td>Mayne Pharma Doxycycline [YT]</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>*11.84</td>
<td>*29.70</td>
<td>19.15</td>
<td>Doryx [YN]</td>
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</tbody>
</table>
**ANTIINFECTIVES FOR SYSTEMIC USE**

**DOXYCYCLINE**

*Note* Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hyclate (hydrochloride)), doxycycline tablet 50 mg (as monohydrate) and doxycycline modified release capsule 50 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

**Restricted benefit**
**Bronchiectasis**
- Patient must be aged 8 years or older.

**Restricted benefit**
**Severe acne**

**Caution** There are concerns about the incidence of benign intracranial hypertension associated with this drug.

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

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

**MINOCYCLINE**

*Clinical criteria:*
- The condition must not be responding to other tetracyclines.

**BETA-LACTAM ANTIBACTERIALS, PENICILLINS**

**Penicillins with extended spectrum**

**AMOXICILLIN**

*amoxicillin 250 mg capsule, 20*
<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Type of Product</th>
<th>Dosage</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><strong>amoxicillin 500 mg capsule, 20</strong></td>
<td>3300Q</td>
<td>1</td>
<td>.</td>
<td>..</td>
<td>13.77</td>
<td>15.06</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>amoxicillin 500 mg/5 mL powder for oral liquid, 100 mL</strong></td>
<td>5225B</td>
<td>1</td>
<td>.</td>
<td>.</td>
<td>#17.36</td>
<td>19.02</td>
</tr>
<tr>
<td></td>
<td><strong>amoxicillin 100 mg/mL powder for oral liquid, 20 mL</strong></td>
<td>1888J</td>
<td>1</td>
<td>.</td>
<td>.</td>
<td>#0.53</td>
<td>#21.77</td>
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<tr>
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<td><strong>amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL</strong></td>
<td>1886G</td>
<td>1</td>
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<td>.</td>
<td>#16.30</td>
<td>17.96</td>
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<tr>
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<td><strong>amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL</strong></td>
<td>3302T</td>
<td>1</td>
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<td>.</td>
<td>#16.30</td>
<td>17.96</td>
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<tr>
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<td><strong>amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL</strong></td>
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<td>18.29</td>
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**AMILOXIN**

*Authority required (STREAMLINED)*

**amoxicillin 1 g tablet, 14**

<table>
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<th>Dosage</th>
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<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
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<td>13.60</td>
<td>14.89</td>
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</table>

**AMOXICILLIN**

*Restricted benefit*

Chronic bronchitis

Clinical criteria:

- Patient must have acute exacerbations of the condition.
### AMOXICILLIN

**Authority required**

Infection suspected or proven to be due to a susceptible organism

**Clinical criteria:**
- The treatment must be for patients who require a liquid formulation and in whom the syrup formulations are unsuitable.

**amoxicillin 100 mg/mL powder for oral liquid, 20 mL**

<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>1</td>
<td>...</td>
<td>13.60</td>
<td>14.89</td>
<td>Amoxycillin Sandoz [BG]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>11.08</td>
<td>14.68</td>
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**amoxicillin 500 mg capsule, 20**

<table>
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<th>Max Qty Packs</th>
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<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>...</td>
<td>15.52</td>
<td>16.81</td>
<td>Alphamox 500 [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>16.58</td>
<td>16.81</td>
<td>Amoxycillin AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Amoxycillin Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cilamox [AL]</td>
</tr>
<tr>
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<td></td>
<td>7.52</td>
<td>23.04</td>
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**amoxicillin 250 mg capsule, 20**

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<tr>
<td>2</td>
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<tr>
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<td>16.81</td>
<td>Amoxycillin AN [EA]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Amoxycillin Sandoz [SZ]</td>
</tr>
<tr>
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<td></td>
<td>Cilamox [AL]</td>
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**amoxicillin 500 mg capsule, 20**

<table>
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<th>Max Qty Packs</th>
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<tr>
<td>1</td>
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<td>13.49</td>
<td>14.78</td>
<td>Alphamox 250 [AF]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>14.96</td>
<td>16.25</td>
<td>Amoxycillin AN [EA]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>APO-Amoxicillin [TX]</td>
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<td></td>
<td>Cilamox [AL]</td>
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<td></td>
<td>3.49</td>
<td>16.98</td>
<td>Amoxil [AS]</td>
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</tbody>
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**amoxicillin 250 mg capsule, 20**

<table>
<thead>
<tr>
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<td>13.49</td>
<td>14.78</td>
<td>Amoxycillin AN [EA]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Amoxycillin Sandoz [SZ]</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>Cilamox [AL]</td>
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<td></td>
<td>3.76</td>
<td>17.53</td>
<td>Amoxil [AS]</td>
</tr>
</tbody>
</table>

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

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

#### Ampicillin 1 g injection, 5 vials

<table>
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<tr>
<td>2977Q</td>
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#### Ampicillin 500 mg injection, 5 vials

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#### Ampicillin 500 mg injection, 5 vials

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>1</td>
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#### Ampicillin 500 mg injection, 5 vials

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>18.27</td>
<td>Austrapen [AL]</td>
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</table>

### Betalactamase sensitive penicillins

### BENZATHINE BENZYL PENICILLIN

#### Benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 mL syringes

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>2267H</td>
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<td>..</td>
<td>304.76</td>
<td>41.00</td>
<td>Bicillin L-A [PF]</td>
</tr>
</tbody>
</table>

#### Benzathine benzylpenicillin tetrahydrate 1.2 million units (1016.6 mg)/2.3 mL injection, 10 x 2.3 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>
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<tr>
<td>5027N</td>
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<td>..</td>
<td>304.76</td>
<td>41.00</td>
<td>Bicillin L-A [PF]</td>
</tr>
</tbody>
</table>

#### Benzathine benzylpenicillin tetrahydrate 600 000 units (517 mg)/1.17 mL injection, 10 x 1.17 mL syringes

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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</tbody>
</table>

#### Benzathine benzylpenicillin tetrahydrate 600 000 units (517 mg)/1.17 mL injection, 10 x 1.17 mL syringes

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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### BENZYL PENICILLIN

#### Benzylpenicillin 3 g injection, 1 vial

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</table>

#### Benzylpenicillin 3 g injection, 1 vial

<table>
<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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<td>BenPen [CS]</td>
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</table>

#### Benzylpenicillin 600 mg injection, 1 vial

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
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<td>71.44</td>
<td>41.00</td>
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#### Benzylpenicillin 600 mg injection, 1 vial

<table>
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<th>Premium $</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>41.00</td>
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### PHENOXYMETHYL PENICILLIN

#### Phenoxymethylpenicillin 250 mg capsule, 50

<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>1789E</td>
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<td>..</td>
<td>16.14</td>
<td>17.43</td>
<td>Cilicaine VK [AF]</td>
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#### Phenoxymethylpenicillin 250 mg capsule, 50

<table>
<thead>
<tr>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>3363B</td>
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<td>16.14</td>
<td>17.43</td>
<td>Cilicaine VK [AF]</td>
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#### Phenoxymethylpenicillin 500 mg capsule, 50

<table>
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<td>19.44</td>
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<td>General Pharmaceutical Benefits</td>
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<tr>
<td>Max Qty Packs</td>
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<tr>
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<td>Max Qty Packs</td>
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<td>19.61</td>
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</tbody>
</table>

- **Phenoxymethylpenicillin**
  - Restricted benefit
  - Recurrent streptococcal infections (including rheumatic fever)
  - Clinical criteria:
    - The treatment must be for prophylaxis.

- **Procaaine Benzylpenicillin**
  - Procaaine benzylpenicillin (procaaine penicillin) 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes
  - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
  - 1794K | 1 | .. | 75.37 | 41.00 | Cilicaine [AF] |
# Antiinfectives for Systemic Use

## Procaine Benzylpenicillin

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<thead>
<tr>
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<th>No of Rpts</th>
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### Beta-Lactamase Resistant Penicillins

## Dicloxacillin

**Restricted Benefit**
Serious staphylococcal infection

### Dicloxacillin 250 mg Capsule, 24

<table>
<thead>
<tr>
<th>Code</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>18.59</td>
<td>17.93</td>
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<td>Distaph 250 [AF]</td>
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### Dicloxacillin 500 mg Capsule, 24

<table>
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<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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<td></td>
<td></td>
<td>22.07</td>
<td>21.41</td>
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<td>Distaph 500 [AF]</td>
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</tbody>
</table>

## Dicloxacillin

**Restricted Benefit**
Serious staphylococcal infection

### Dicloxacillin 250 mg Capsule, 24

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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<td>18.59</td>
<td>17.93</td>
<td></td>
<td>Distaph 250 [AF]</td>
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### Dicloxacillin 500 mg Capsule, 24

<table>
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<th>No of Rpts</th>
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<th>DPMO $</th>
<th>MRVSN $</th>
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<td>22.07</td>
<td>21.41</td>
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<td>Distaph 500 [AF]</td>
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## Dicloxacillin

**Authority Required (Streamlined)**
Osteomyelitis

### Dicloxacillin 500 mg Capsule, 24

<table>
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<th>Code</th>
<th>Max Qty Packs</th>
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<tr>
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<td></td>
<td></td>
<td>32.12</td>
<td>29.51</td>
<td></td>
<td>Distaph 500 [AL]</td>
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</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.

**Note**
Pharmaceutical benefits that have the form flucloxacillin 1 g injection in a pack size of 5 can be substituted for a pack size of 10 in the case of a shortage.

### Flucloxacillin 1 g Injection, 5 vials

<table>
<thead>
<tr>
<th>Code</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>1525G</td>
<td>1</td>
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<td>20.60</td>
<td>21.89</td>
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<td>Flucil [AS]</td>
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### Flucloxacillin 1 g Injection, 5 vials

<table>
<thead>
<tr>
<th>Code</th>
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<th>No of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
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<td>21.89</td>
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<td>Flucil [AS]</td>
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### Flucloxacillin 1 g Injection, 10 vials

<table>
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<th>DPMO $</th>
<th>MRVSN $</th>
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<tbody>
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<td>26.53</td>
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<td>Flubiclox [JU]</td>
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### Flucloxacillin 1 g Injection, 10 vials

<table>
<thead>
<tr>
<th>Code</th>
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<td>26.53</td>
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</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 infection
## 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 infection

<table>
<thead>
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<tr>
<td><strong>DPMQ $</strong></td>
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<td><strong>MRVSN $</strong></td>
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</tr>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
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</tr>
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<table>
<thead>
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<th>Flucloxacillin 250 mg/5 mL powder for oral liquid, 100 mL</th>
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<tbody>
<tr>
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### FLUCLOXACILLIN

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Note** Pharmaceutical benefits that have the form flucloxacillin 250 mg capsule, 28 and pharmaceutical benefits that have the form flucloxacillin 250 mg capsule, 24 are equivalent for the purposes of substitution.

### Restricted benefit

Serious staphylococcal infection

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<td><strong>DPMQ $</strong></td>
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<tr>
<td><strong>MRVSN $</strong></td>
<td></td>
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<tr>
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<table>
<thead>
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<td>25.78</td>
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<td>Flucil [LN]</td>
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### FLUCLOXACILLIN

**Caution** Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Note** Pharmaceutical benefits that have the form flucloxacillin 500 mg capsule, 24 and pharmaceutical benefits that have the form flucloxacillin 500 mg capsule, 100 are equivalent for the purposes of substitution.

### Restricted benefit

Serious staphylococcal infection

<table>
<thead>
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<td>a APO-Flucloxacillin [TX]</td>
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<td>a Staphylex 250 [AF]</td>
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<tr>
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<td>* Flopen [AL]</td>
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</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.

**Note** Pharmaceutical benefits that have the form flucloxacillin 250 mg capsule, 28 and pharmaceutical benefits that have the form flucloxacillin 250 mg capsule, 24 are equivalent for the purposes of substitution.

### Restricted benefit

Serious staphylococcal infection

<table>
<thead>
<tr>
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<tr>
<td>* Flopen [AL]</td>
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</tr>
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</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.

**Note** Pharmaceutical benefits that have the form flucloxacillin 500 mg capsule, 24 and pharmaceutical benefits that have the form flucloxacillin 500 mg capsule, 100 are equivalent for the purposes of substitution.

### Restricted benefit

Serious staphylococcal infection
### AMOXICILLIN + CLAVULANIC ACID

#### Authority required (STREAMLINED)

#### Clinical criteria:
- Patient must have periorbital (preseptal) cellulitis; OR
- Patient must have postpartum endometritis; OR
- Patient must have an exacerbation of bronchiectasis; OR
- Patient must have pyelonephritis; OR
- Patient must have pneumonia acquired in hospital or aged care; OR
- Patient must have a diabetic foot infection; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

#### Combinations of penicillins, incl. beta-lactamase inhibitors

**AMOXICILLIN + CLAVULANIC ACID**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>AlphaClav Duo Forte [AF]</td>
<td>AMCLAVOX DUO FORTE 875/125 [RW]</td>
</tr>
<tr>
<td>AMOXYCXLAV AMNEAL 875/125 [ED]</td>
<td>Amoxycillin/Clavulanic Acid 500/125 [TY]</td>
</tr>
<tr>
<td>AMOXICLAV generichealth 875/125 [HQ]</td>
<td>APO-Amoxicillin and Clavulanic Acid [TX]</td>
</tr>
<tr>
<td>Curam Duo Forte 875/125 [SZ]</td>
<td>Augmentin Duo forte [AS]</td>
</tr>
</tbody>
</table>

#### AMOXICILLIN + CLAVULANIC ACID

#### Authority required (STREAMLINED)

#### Clinical criteria:
- Patient must be a male with acute cystitis; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

**AMOXICILLIN + CLAVULANIC ACID**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>AlphaClav Duo [AF]</td>
<td>AMCLAVOX DUO 500/125 [RW]</td>
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<td>AMOXYCXLAV AMNEAL 500/125 [ED]</td>
<td>Amoxycillin/Clavulanic Acid 500/125 [TY]</td>
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<td>Amoxyclav AN 500/125 [EA]</td>
<td>APO-Amoxicillin and Clavulanic Acid 500/125 [TX]</td>
</tr>
<tr>
<td>Curam Duo 500/125 [SZ]</td>
<td>Augmentin Duo [AS]</td>
</tr>
</tbody>
</table>

#### AMOXICILLIN + CLAVULANIC ACID

**Caution** Hepatotoxicity has been reported with this drug.

**Restricted benefit** Infections where resistance to amoxicillin is suspected

**Restricted benefit** Infections where resistance to amoxicillin is proven

---

**FLUCLOXACillin**

**Caution** Severe cholestatic jaundice has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Note** Pharmaceutical benefits that have the form flucloxacillin 500 mg capsule, 24 and pharmaceutical benefits that have the form flucloxacillin 500 mg capsule, 100 are equivalent for the purposes of substitution.
### Antiinfectives for Systemic Use

**General Pharmaceutical Benefits**

#### Amoxicillin + Clavulanic Acid

**Caution** Hepatotoxicity has been reported with this drug.

**Restricted benefit** Infection where resistance to amoxicillin is suspected

**Restricted benefit** Infections where resistance to amoxicillin is proven

#### Amoxicillin 400 mg/5 mL + Clavulanic Acid 57 mg/5 mL Powder for Oral Liquid, 60 mL

<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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</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>#16.96</td>
<td>18.62</td>
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</table>

#### Amoxicillin 125 mg/5 mL + Clavulanic Acid 31.25 mg/5 mL Powder for Oral Liquid, 75 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>#16.64</td>
<td>18.30</td>
<td>Curam [SZ]</td>
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</table>

#### Amoxicillin 400 mg/5 mL + Clavulanic Acid 57 mg/5 mL Powder for Oral Liquid, 60 mL

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<tr>
<th>Max Qty Packs</th>
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<td>#16.96</td>
<td>18.62</td>
<td>* Augmentin Duo 400 [AS]</td>
</tr>
</tbody>
</table>

#### Amoxicillin 125 mg/5 mL + Clavulanic Acid 31.25 mg/5 mL Powder for Oral Liquid, 75 mL

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<th>Max Qty Packs</th>
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#### Amoxicillin 500 mg + Clavulanic Acid 125 mg Tablet, 10

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<tr>
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<td>Amoxyclav AN 500/125 [EA]</td>
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<td>APO-Amoxycillin/ Clavulanic Acid 500/125 [TX]</td>
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#### Amoxicillin 875 mg + Clavulanic Acid 125 mg Tablet, 10

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#### Amoxicillin 500 mg + Clavulanic Acid 125 mg Tablet, 10

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#### Amoxicillin 875 mg + Clavulanic Acid 125 mg Tablet, 10

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

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

**ANTIINFECTIVES FOR SYSTEMIC USE**

**Schedule of Pharmaceutical Benefits – December 2020**

#### OTHER BETA-LACTAM ANTIBACTERIALS

**First-generation cephalosporins**

- **CEFALEXIN**
  - **cephalexin 250 mg capsule, 20**
    - 3317N
      - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer
      - 1 | | 13.73 | 15.02 | | APO-Cephalexin [TX] | Cephalexin AN [EA]
      - | | 3.76 | 15.02 | | Keflex [AS] |
  - **cephalexin 500 mg capsule, 20**
    - 3318P
      - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer
      - 1 | | 13.88 | 15.17 | | APO-Cephalexin [TX] | Cephalexin Sandoz [SZ]
      - | | 5.47 | 15.17 | | Keflex [AS] |
  - **cephalexin 125 mg/5 mL powder for oral liquid, 100 mL**
    - 3094W
      - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer
      - ‡1 | 1 | #16.88 | 18.54 | | Cefalexin Sandoz [SZ] | Ibilex 125 [AF]
      - | | 4.15 | 18.54 | | Keflex [AS] |
    - 3319Q
      - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer
      - ‡1 | | #16.88 | 18.54 | | Cefalexin Sandoz [SZ] | Ibilex 125 [AF]
      - | | 4.15 | 18.54 | | Keflex [AS] |
  - **cephalexin 250 mg/5 mL powder for oral liquid, 100 mL**
    - 3095X
      - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer
      - ‡1 | 1 | #17.18 | 18.84 | | Cefalexin Sandoz [SZ] | Ibilex 250 [AF]
      - | | 5.69 | 18.84 | | Keflex [AS] |
    - 3320R
      - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer
      - ‡1 | | #17.18 | 18.84 | | Cefalexin Sandoz [SZ] | Ibilex 250 [AF]
      - | | 5.69 | 18.84 | | Keflex [AS] |

**Authority required (STREAMLINED)**

- **CEFALEXIN**
  - **6188 Osteomyelitis**
    - **cephalexin 500 mg capsule, 20**
      - 10778Q
        - Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer
        - 2 | 1 | $15.74 | 17.03 | | APO-Cephalexin [TX] | Cephalexin Sandoz [SZ]
        - | | 10.94 | 17.03 | | Keflex [AS] |

**Authority required (STREAMLINED)**

- **CEFALEXIN**
  - **10410 Infection**
    - Clinical criteria:
      - Patient must have a pin-site infection; OR
      - Patient must have an infection following cardiac device insertion; OR
      - Patient must have acute otitis externa; OR
      - Patient must have streptococcal pharyngitis or tonsillitis; OR
      - Patient must have mastitis; OR
      - Patient must have periorbital (preseptal) cellulitis; OR
      - Patient must have acute rheumatic fever; OR
      - Patient must have a diabetic foot infection; OR

### Notes

- ‡ Authority required (STREAMLINED)
- * Premium only
- $ Premium and DPMQ
- † Authority required
- Patient must have a widespread infection of dermatitis; OR
- Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection; OR
- Patient must have impetigo; OR
- Patient must have pyelonephritis; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

Midwives may prescribe under this item for the treatment of mastitis only.

cefalexin 500 mg capsule, 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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<th>Brand Name and Manufacturer</th>
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<td>Cefalexin Sandoz [SZ]</td>
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<td>Cephalexin generichealth [GQ]</td>
<td>Ibilex 500 [AF]</td>
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</tr>
</tbody>
</table>

**CEFALEXIN**

**Authority required (STREAMLINED)**

**10412**

Infection

**Clinical criteria:**
- Patient must have impaired renal function, **AND**
- Patient must have a pin-site infection; OR
- Patient must have an infection following cardiac device insertion; OR
- Patient must have acute otitis externa; OR
- Patient must have streptococcal pharyngitis or tonsillitis; OR
- Patient must have mastitis; OR
- Patient must have periorbital (preseptal) cellulitis; OR
- Patient must have acute rheumatic fever; OR
- Patient must have a diabetic foot infection; OR
- Patient must have a widespread infection of dermatitis; OR
- Patient must require treatment for prophylaxis for invasive group A streptococcal (iGAS) infection; OR
- Patient must have impetigo; OR
- Patient must have pyelonephritis; OR
- Patient must have a condition requiring prolonged oral antibiotic therapy.

Midwives may prescribe under this item for the treatment of mastitis only, where the patient has impaired renal function.

cefalexin 250 mg capsule, 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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<td></td>
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<td>16.73</td>
<td></td>
<td>Cephalexin AN [EA]</td>
<td>Ibilex 250 [AF]</td>
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**CEFALEXIN**

**Authority required (STREAMLINED)**

**4243**

Prophylaxis of urinary tract infection

cefalexin 250 mg capsule, 20

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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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</tbody>
</table>

**CEFALEXIN**

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

cefalexin 250 mg capsule, 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>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3058Y</td>
<td></td>
<td>3.76</td>
<td>17.49</td>
<td>15.02</td>
<td>Keflex [AS]</td>
<td></td>
</tr>
</tbody>
</table>

**CEFALEXIN**

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

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

cefalexin 500 mg capsule, 20

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3119E</td>
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<td>15.17</td>
<td>Keflex [AS]</td>
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General Pharmaceutical Benefits 221
## ANTIINFECTIVES FOR SYSTEMIC USE

### CEFALOTIN

<table>
<thead>
<tr>
<th>Cefalotin 1 g injection, 10 vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>2964B</td>
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<table>
<thead>
<tr>
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<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>26.49</td>
<td>27.78</td>
<td>DBL Cephalothin [PF]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cefalotin 1 g injection, 10 vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>3376Q</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<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>..</td>
<td>26.49</td>
<td>27.78</td>
<td>DBL Cephalothin [PF]</td>
</tr>
</tbody>
</table>

### CEFAZOLIN

<table>
<thead>
<tr>
<th>Cefazolin 1 g injection, 5 vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1799Q</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*21.80</td>
<td>23.09</td>
<td>Cefazolin-AFT [AE]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cefazolin 500 mg injection, 5 vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>5477G</td>
</tr>
</tbody>
</table>

<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>2</td>
<td>..</td>
<td>..</td>
<td>*18.32</td>
<td>19.61</td>
<td>Cefazolin-AFT [AE]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cefazolin 2 g injection, 1 vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>5479J</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>..</td>
<td>..</td>
<td>*39.84</td>
<td>41.00</td>
<td>* Cephazolin Alphapharm [AF]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cefazolin 2 g injection, 10 vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>12115P</td>
</tr>
</tbody>
</table>

<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>..</td>
<td>39.87</td>
<td>41.00</td>
<td>* Cephazolin Alphapharm [AF]</td>
</tr>
</tbody>
</table>

### CEFAZOLIN

**Note** Pharmaceutical benefits that have the form cefazolin 2 g injection, 1 vial, and pharmaceutical benefits that have the form cefazolin 2 g injection, 10 vials are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
<th>Cefazolin 2 g injection, 1 vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>5479J</td>
</tr>
</tbody>
</table>

<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>10</td>
<td>..</td>
<td>..</td>
<td>*39.84</td>
<td>41.00</td>
<td>* Cephazolin Alphapharm [AF]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cefazolin 2 g injection, 10 vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>12115P</td>
</tr>
</tbody>
</table>

<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>..</td>
<td>39.87</td>
<td>41.00</td>
<td>* Cephazolin Alphapharm [AF]</td>
</tr>
</tbody>
</table>

### CEFAZOLIN

**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>Cefazolin 500 mg injection, 5 vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1256D</td>
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</tbody>
</table>

<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>2</td>
<td>..</td>
<td>..</td>
<td>*18.32</td>
<td>19.61</td>
<td>Cefazolin-AFT [AE]</td>
</tr>
</tbody>
</table>

### CEFAZOLIN

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

<table>
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<th>Cefazolin 500 mg injection, 5 vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1256D</td>
</tr>
</tbody>
</table>

<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>2</td>
<td>..</td>
<td>..</td>
<td>*18.32</td>
<td>19.61</td>
<td>Cefazolin-AFT [AE]</td>
</tr>
</tbody>
</table>
**ANTIINFECTIVES FOR SYSTEMIC USE**

### CEFAZOLIN

**Note**
Pharmaceutical benefits that have the form cefazolin 2 g injection, 1 vial, and pharmaceutical benefits that have the form cefazolin 2 g injection, 10 vials 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.

**Restricted benefit**
Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**
Septicaemia, suspected

**Restricted benefit**
Septicaemia, proven

---

### CEFACLOR

**Caution**
Serum sickness-like reactions have been reported with this drug, especially in children.

**cefACLOR 125 mg/5 mL powder for 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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>#18.26</td>
<td>19.92</td>
<td></td>
<td>Aclor 125 [MQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>APO-Cefaclor [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Keflor [AF]</td>
</tr>
</tbody>
</table>

8.00  
#26.26  
19.92  
Ceclor [AL]

**cefACLOR 250 mg/5 mL powder for oral liquid, 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>1</td>
<td>1</td>
<td>#18.48</td>
<td>20.14</td>
<td></td>
<td>Aclor 250 [MQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>APO-Cefaclor [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Keflor [AF]</td>
</tr>
</tbody>
</table>

8.00  
#26.48  
20.14  
Ceclor [AL]

**cefACLOR 375 mg modified release tablet, 10**

<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>1</td>
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<td>15.78</td>
<td>17.07</td>
<td></td>
<td>APO-Cefaclor CD [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cefaclor GH [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Karlor CD [MQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Keflor CD [AF]</td>
</tr>
</tbody>
</table>

8.00  
23.78  
17.07  
Ceclor CD [AL]

---

General Pharmaceutical Benefits 223
**ANTIINFECTIVES FOR SYSTEMIC USE**

### CEFUROXIME

- **Cefuroxime 125 mg/5 mL powder for oral liquid, 70 mL**
  - 2002J
  - Max Qty Packs: 1
  - No. of Rpts: 1
  - Premium $: 23.52
  - DPMQ $: 23.52
  - MRVSN $: 25.18
  - Brand Name and Manufacturer: Zinnat [AS]

- **Cefuroxime 125 mg/5 mL powder for oral liquid, 70 mL**
  - 5499K
  - Max Qty Packs: 1
  - No. of Rpts: 1
  - Premium $: 23.52
  - DPMQ $: 23.52
  - MRVSN $: 25.18
  - Brand Name and Manufacturer: Zinnat [AS]

- **Cefuroxime 250 mg tablet, 14**
  - 5052X
  - Max Qty Packs: 1
  - No. of Rpts: 1
  - Premium $: 22.11
  - DPMQ $: 22.11
  - MRVSN $: 23.40
  - Brand Name and Manufacturer: Pharmacor Cefuroxime [CR]

- **Cefuroxime 250 mg tablet, 14**
  - 8292K
  - Max Qty Packs: 1
  - No. of Rpts: 1
  - Premium $: 22.11
  - DPMQ $: 22.11
  - MRVSN $: 23.40
  - Brand Name and Manufacturer: Pharmacor Cefuroxime [CR]

- **Cefuroxime 125 mg/5 mL powder for oral liquid, 100 mL**
  - 11191B
  - Max Qty Packs: 1
  - No. of Rpts: 1
  - Premium $: 27.21
  - DPMQ $: 27.21
  - MRVSN $: 28.87
  - Brand Name and Manufacturer: Zinnat [AS]

- **Cefuroxime 125 mg/5 mL powder for oral liquid, 100 mL**
  - 11192C
  - Max Qty Packs: 1
  - No. of Rpts: 1
  - Premium $: 27.21
  - DPMQ $: 27.21
  - MRVSN $: 28.87
  - Brand Name and Manufacturer: Zinnat [AS]

- **Cefuroxime 250 mg tablet, 20**
  - 11227X
  - Max Qty Packs: 1
  - No. of Rpts: 1
  - Premium $: 26.43
  - DPMQ $: 26.43
  - MRVSN $: 27.72
  - Brand Name and Manufacturer: Pharmacor Cefuroxime [CR]
  - Brand Name and Manufacturer: Zinnat [AS]

- **Cefuroxime 250 mg tablet, 20**
  - 11228Y
  - Max Qty Packs: 1
  - No. of Rpts: 1
  - Premium $: 26.43
  - DPMQ $: 26.43
  - MRVSN $: 27.72
  - Brand Name and Manufacturer: Pharmacor Cefuroxime [CR]
  - Brand Name and Manufacturer: Zinnat [AS]

### Restricted benefit

**Third-generation cephalosporins**

- **Cefotaxime 1 g injection, 10 vials**
  - 1768C
  - Max Qty Packs: 1
  - No. of Rpts: 1
  - Premium $: 28.04
  - DPMQ $: 28.04
  - MRVSN $: 29.33
  - Brand Name and Manufacturer: DBL Cefotaxime [PF]

- **Cefotaxime 2 g injection, 10 vials**
  - 1769D
  - Max Qty Packs: 1
  - No. of Rpts: 1
  - Premium $: 35.67
  - DPMQ $: 35.67
  - MRVSN $: 36.96
  - Brand Name and Manufacturer: DBL Cefotaxime [PF]

### Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner 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 1 g injection, 10 vials**
  - 1758M
  - Max Qty Packs: 1
  - No. of Rpts: 1
  - Premium $: 28.04
  - DPMQ $: 28.04
  - MRVSN $: 29.33
  - Brand Name and Manufacturer: DBL Cefotaxime [PF]
**ANTIIINFECTIVES FOR SYSTEMIC USE**

**Cefotaxime 2 g injection, 10 vials**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Premium $</th>
</tr>
</thead>
<tbody>
<tr>
<td>DBL Cefotaxime [PF]</td>
<td>35.67</td>
<td>36.96</td>
<td></td>
</tr>
</tbody>
</table>

**CEFTRIAXONE**

**Gonorrhoea**

**Ceftriaxone 500 mg injection, 1 vial**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Premium $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftriaxone-AFT [AE]</td>
<td>13.08</td>
<td>14.37</td>
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</tr>
</tbody>
</table>

**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.

**Note**

Pharmaceutical benefits that have the form ceftriaxone 1 g injection, 1 vial, pharmaceutical benefits that have the form ceftriaxone 1 g injection, 5 vials, and pharmaceutical benefits that have the form ceftriaxone 1 g injection, 10 vials are equivalent for the purposes of substitution.

**Limited benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**Ceftriaxone 500 mg injection, 1 vial**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Premium $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftriaxone-AFT [AE]</td>
<td>17.34</td>
<td>18.63</td>
<td></td>
</tr>
</tbody>
</table>

**CEFTRIAXONE**

**Note**

Pharmaceutical benefits that have the form ceftriaxone 2 g injection, 1 vial, pharmaceutical benefits that have the form ceftriaxone 2 g injection, 5 vials, and pharmaceutical benefits that have the form ceftriaxone 2 g injection, 10 vials 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.

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**Ceftriaxone 1 g injection, 1 vial**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Premium $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftriaxone-AFT [AE]</td>
<td>23.04</td>
<td>24.33</td>
<td></td>
</tr>
</tbody>
</table>

**Ceftriaxone 1 g injection, 5 vials**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Premium $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftriaxone Alphapharm [AF]</td>
<td>23.04</td>
<td>24.33</td>
<td></td>
</tr>
</tbody>
</table>

**Ceftriaxone 1 g injection, 10 vials**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Premium $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceftriaxone Alphapharm [AF]</td>
<td>28.26</td>
<td>29.55</td>
<td></td>
</tr>
</tbody>
</table>
Septicaemia, proven

**ceftriaxone 2 g injection, 1 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>5</td>
<td>..</td>
<td>..</td>
<td>*23.19</td>
<td>24.48</td>
<td>* Ceftriaxone-AFT [AE]</td>
</tr>
</tbody>
</table>

**ceftriaxone 2 g injection, 10 vials**

<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>0.5</td>
<td>..</td>
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<td>*28.40</td>
<td>29.69</td>
<td>* Ceftriaxone Alphapharm [AF]</td>
</tr>
</tbody>
</table>

**ceftriaxone 2 g injection, 5 vials**

<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>23.15</td>
<td>24.44</td>
<td>* Ceftriaxone Alphapharm [AF]</td>
</tr>
</tbody>
</table>

---

### Fourth-generation cephalosporins

---

### CEFEPIME

**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.

---

**Authority required**

Febrile neutropenia

**cefepime 1 g injection, 1 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>
<tbody>
<tr>
<td>10</td>
<td>..</td>
<td>..</td>
<td>*52.14</td>
<td>41.00</td>
<td>* Cefepime-AFT [AE]</td>
<td>* Cefepime Alphapharm [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Cefepime Kabi [PK]</td>
<td>* Omegapharm Pty Ltd [OE]</td>
</tr>
</tbody>
</table>

**cefepime 2 g injection, 1 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>
<tbody>
<tr>
<td>10</td>
<td>..</td>
<td>..</td>
<td>*81.64</td>
<td>41.00</td>
<td>* Cefepime-AFT [AE]</td>
<td>* Cefepime Alphapharm [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Cefepime Kabi [PK]</td>
<td>* Omegapharm Pty Ltd [OE]</td>
</tr>
</tbody>
</table>

### SULFONAMIDES AND TRIMETHOPRIM

**Trimethoprim and derivatives**

---

### TRIMETHOPRIM

**trimethoprim 300 mg tablet, 7**

<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>1</td>
<td>..</td>
<td>13.72</td>
<td>15.01</td>
<td>* Alprim [AF]</td>
<td>* Trimethoprim Mylan [AL]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3.68</td>
<td>17.40</td>
<td>* Triprim [RW]</td>
<td></td>
</tr>
</tbody>
</table>

---

### TRIMETHOPRIM

**Authority required (STREAMLINED)**

4243

Prophylaxis of urinary tract infection

**trimethoprim 300 mg tablet, 7**

<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>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>2</td>
<td>..</td>
<td>*15.42</td>
<td>16.71</td>
<td>* Alprim [AF]</td>
<td>* Trimethoprim Mylan [AL]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>7.36</td>
<td>22.78</td>
<td>* Triprim [RW]</td>
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</tbody>
</table>

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### TRIMETHOPRIM

**Restricted benefit**

Prostatitis

**trimethoprim 300 mg tablet, 7**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4</td>
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<td>*18.82</td>
<td>20.11</td>
<td>* Alprim [AF]</td>
<td>* Trimethoprim Mylan [AL]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>14.72</td>
<td>33.54</td>
<td>* Triprim [RW]</td>
<td></td>
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</tbody>
</table>

---

### 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 40 mg/5 mL + sulfamethoxazole 200 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>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>20.32</td>
<td>21.61</td>
<td>Sepritin [RW]</td>
</tr>
</tbody>
</table>
trimethoprim 40 mg/5 mL + sulfamethoxazole 200 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>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>20.32</td>
<td>21.61</td>
<td></td>
<td>Septrin [RW]</td>
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</table>

trimethoprim 160 mg + sulfamethoxazole 800 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>
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<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>13.91</td>
<td>15.20</td>
<td>^4,17</td>
<td>^4,17</td>
</tr>
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</table>

trimethoprim 160 mg + sulfamethoxazole 800 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>1</td>
<td>..</td>
<td>13.91</td>
<td>15.20</td>
<td>^4,17</td>
<td>^4,17</td>
</tr>
</tbody>
</table>

TRIMETHOPRIM + SULFAMETHOXAZOLE

Caution: There is an increased risk of severe adverse reactions with this combination in the elderly.

Authority required (STREAMLINED) 6201

Prophylaxis of Pneumocystis jiroveci pneumonia

trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
<td>3</td>
<td>2</td>
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<td></td>
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MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

AZITHROMYCIN

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

Restricted benefit

Trachoma

azithromycin 200 mg/5 mL powder for oral liquid, 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>
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</thead>
<tbody>
<tr>
<td>^1</td>
<td>..</td>
<td>#27.36</td>
<td>29.02</td>
<td></td>
<td>Zithromax [PF]</td>
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</tbody>
</table>

azithromycin 500 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>1</td>
<td>2</td>
<td>16.30</td>
<td>17.59</td>
<td></td>
<td>APO-Azithromycin [TX]</td>
</tr>
</tbody>
</table>

AZITHROMYCIN

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

Restricted benefit

Urethritis

Clinical criteria:
- The condition must be uncomplicated and due to Chlamydia trachomatis.

Restricted benefit

Cervicitis

Clinical criteria:
- The condition must be uncomplicated and due to Chlamydia trachomatis.

azithromycin 500 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>
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</thead>
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<tr>
<td>1</td>
<td>..</td>
<td>16.30</td>
<td>17.59</td>
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<td>APO-Azithromycin [TX]</td>
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</table>

CLARITHROMYCIN

clarithromycin 250 mg tablet, 14

<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>^3</td>
<td>1</td>
<td>3.49</td>
<td>18.47</td>
<td>16.27</td>
<td>Klacid [GO]</td>
</tr>
</tbody>
</table>
### CLARITHROMYCIN

**Restricted benefit**

**Bordetella pertussis**

**Restricted benefit**

Atypical mycobacterial infections

<table>
<thead>
<tr>
<th>clarithromycin 250 mg/5 mL powder for oral liquid, 50 mL</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>9192T</td>
<td>1</td>
<td>..</td>
<td>#31.03</td>
<td>32.69</td>
<td>Klacid [GO]</td>
<td></td>
</tr>
</tbody>
</table>

### ERYTHROMYCIN

erythromycin 250 mg enteric capsule, 25

<table>
<thead>
<tr>
<th>erythromycin 250 mg enteric capsule, 25</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>1404X</td>
<td>1</td>
<td>1</td>
<td>22.20</td>
<td>23.49</td>
<td>Eryc [YN]</td>
<td>Mayne Pharma Erythromycin [YT]</td>
</tr>
<tr>
<td>3325B</td>
<td>1</td>
<td>..</td>
<td>22.20</td>
<td>23.49</td>
<td>Eryc [YN]</td>
<td>Mayne Pharma Erythromycin [YT]</td>
</tr>
</tbody>
</table>

### ERYTHROMYCIN

Authority required (STREAMLINED)

6160

Severe acne

Clinical criteria:

- The condition must be one in which tetracycline therapy is inappropriate.

<table>
<thead>
<tr>
<th>erythromycin 250 mg enteric capsule, 25</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>10780J</td>
<td>2</td>
<td>5</td>
<td>*32.38</td>
<td>33.67</td>
<td>Eryc [YN]</td>
<td>Mayne Pharma Erythromycin [YT]</td>
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### ERYTHROMYCIN ETHYLSUCCINATE

<table>
<thead>
<tr>
<th>erythromycin (as ethylsuccinate) 200 mg/5 mL powder for oral liquid, 100 mL</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>
<tr>
<td>2424N</td>
<td>1</td>
<td>1</td>
<td>#19.72</td>
<td>21.38</td>
<td>E-Mycin 200 [AF]</td>
<td></td>
</tr>
<tr>
<td>3334L</td>
<td>1</td>
<td>..</td>
<td>#19.72</td>
<td>21.38</td>
<td>E-Mycin 200 [AF]</td>
<td></td>
</tr>
<tr>
<td>2428T</td>
<td>1</td>
<td>1</td>
<td>#21.03</td>
<td>22.69</td>
<td>E-Mycin 400 [AF]</td>
<td></td>
</tr>
<tr>
<td>3337P</td>
<td>1</td>
<td>..</td>
<td>#21.03</td>
<td>22.69</td>
<td>E-Mycin 400 [AF]</td>
<td></td>
</tr>
<tr>
<td>2750R</td>
<td>1</td>
<td>1</td>
<td>16.92</td>
<td>18.21</td>
<td>E-Mycin [AF]</td>
<td></td>
</tr>
<tr>
<td>3336N</td>
<td>1</td>
<td>..</td>
<td>16.92</td>
<td>18.21</td>
<td>E-Mycin [AF]</td>
<td></td>
</tr>
</tbody>
</table>

### ERYTHROMYCIN ETHYLSUCCINATE

Authority required (STREAMLINED)

6160

Severe acne

Clinical criteria:

- The condition must be one in which tetracycline therapy is inappropriate.
### ROXITHROMYCIN

**roxithromycin 150 mg tablet, 10**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>APO-Roxithromycin [TX]</td>
<td>14.50</td>
<td>15.79</td>
<td></td>
</tr>
<tr>
<td>Roxar 150 [RW]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roxithromycin AN [EA]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roxithromycin Sandoz [SZ]</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**roxithromycin 300 mg tablet, 5**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>APO-Roxithromycin [TX]</td>
<td>14.50</td>
<td>15.79</td>
<td></td>
</tr>
<tr>
<td>Roxar 300 [RW]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roxithromycin AN [EA]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roxithromycin Sandoz [SZ]</td>
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<td></td>
</tr>
</tbody>
</table>

**roxithromycin 50 mg dispersible tablet, 10**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rulide [SW]</td>
<td>17.65</td>
<td>18.94</td>
<td></td>
</tr>
</tbody>
</table>

### ROXITHROMYCIN

**Authority required (STREAMLINED)**

**Infection**

**Clinical criteria:**
- Patient must have a condition requiring prolonged oral antibiotic therapy.

**roxithromycin 150 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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</thead>
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<td>18.27</td>
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</tr>
<tr>
<td>Roxar 150 [RW]</td>
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</tr>
<tr>
<td>Roxithromycin AN [EA]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roxithromycin Sandoz [SZ]</td>
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</table>

**roxithromycin 300 mg tablet, 5**

<table>
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<tr>
<td>Roxar 300 [RW]</td>
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<td></td>
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</tr>
<tr>
<td>Roxithromycin AN [EA]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roxithromycin Sandoz [SZ]</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

### ROXITHROMYCIN

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

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

**roxithromycin 150 mg tablet, 10**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
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<td>Roxar 150 [RW]</td>
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</tr>
<tr>
<td>Roxithromycin AN [EA]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roxithromycin Sandoz [SZ]</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**roxithromycin 300 mg tablet, 5**

<table>
<thead>
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</tr>
<tr>
<td>Roxar 300 [RW]</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Roxithromycin AN [EA]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roxithromycin Sandoz [SZ]</td>
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<td></td>
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**roxithromycin 50 mg dispersible tablet, 10**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rulide D [SW]</td>
<td>17.65</td>
<td>18.94</td>
<td></td>
</tr>
</tbody>
</table>

### Lincosamides

- **RP**
- **NP**
- **DP**
ANTIINFECTIVES FOR SYSTEMIC USE

**CLINDAMYCIN**

*Restricted benefit*
Gram-positive coccal infections

**Clinical criteria:**
- The condition must not be able to be treated safely and effectively with a penicillin.

### clindamycin 150 mg capsule, 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>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5057E</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>18.89</td>
<td>20.18</td>
<td>* APO-Clindamycin [TX]</td>
<td>* Calindamin [RW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Clindamycin BNM [BZ]</td>
<td>* Clindamycin LU [LV]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Clindamycy [AF]</td>
<td>* Dalacin C [PF]</td>
</tr>
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### clindamycin 150 mg capsule, 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>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>3138E</td>
<td>2</td>
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<td>25.76</td>
<td>27.05</td>
<td>* APO-Clindamycin [TX]</td>
<td>* Calindamin [RW]</td>
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<td></td>
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<td></td>
<td></td>
<td>* Clindamycin BNM [BZ]</td>
<td>* Clindamycin LU [LV]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Clindamycy [AF]</td>
<td>* Dalacin C [PF]</td>
</tr>
</tbody>
</table>

### LINCOMYCIN

*Note* Pharmaceutical benefits that have the form lincomycin 600 mg/2 mL injection, 5 x 2 mL vials and pharmaceutical benefits that have the form lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules are equivalent for the purposes of substitution.

#### lincomycin 600 mg/2 mL injection, 5 x 2 mL vials

<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>2530E</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>97.80</td>
<td>41.00</td>
<td>* Lincocin [PF]</td>
</tr>
</tbody>
</table>

#### lincomycin 600 mg/2 mL injection, 5 x 2 mL ampoules

<table>
<thead>
<tr>
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<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>11366F</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>97.80</td>
<td>41.00</td>
<td>* LINCOMYCIN SXP [XC]</td>
</tr>
<tr>
<td>11380Y</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>97.80</td>
<td>41.00</td>
<td>* LINCOMYCIN SXP [XC]</td>
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</tbody>
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**AMINOGLYCOSIDE ANTIBACTERIALS**

*Other aminoglycosides*

#### GENTAMICIN

*gentamicin 80 mg/2 mL injection, 10 x 2 mL ampoules*

<table>
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<tr>
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<th>Packs</th>
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<tr>
<td>2824P</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>23.54</td>
<td>24.83</td>
<td>Pfizer Australia Pty Ltd [PF]</td>
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</tbody>
</table>

**TOBRAMYCIN**

*Restricted benefit*
Pseudomonas aeruginosa infection

**Clinical criteria:**
- Patient must have cystic fibrosis, AND
- The treatment must be systemic.

#### tobramycin 500 mg/5 mL injection, 10 x 5 mL vials

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
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<tr>
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<td>..</td>
<td>285.99</td>
<td>41.00</td>
<td>Tobra-Day [FF]</td>
</tr>
</tbody>
</table>

**TOBRAMYCIN**

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

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

**Authority required (STREAMLINED)**

5520
Proven Pseudomonas aeruginosa infection

**Clinical criteria:**
- Patient must have cystic fibrosis, **AND**
- The treatment must be for management.

### Tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tr>
<td>5442K</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td>* Tobramycin WKT [LI]</td>
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<td></td>
<td></td>
<td>* TOBRAMYCIN SUN [RA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* TOBRAMYCIN WOCKHARDT [WC]</td>
</tr>
</tbody>
</table>

#### TOBRAMYCIN

**Restricted benefit**

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

### Tobramycin 80 mg/2 mL injection, 5 x 2 mL vials

<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>1356J</td>
<td>2</td>
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<td>*51.82</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Tobramycin Mylan [AF]</td>
</tr>
</tbody>
</table>

### Tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5

<table>
<thead>
<tr>
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<th>DPMO ($)</th>
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<tbody>
<tr>
<td>8872Y</td>
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<td>*55.60</td>
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<td>Pfizer Australia Pty Ltd [PF]</td>
</tr>
</tbody>
</table>

#### TOBRAMYCIN

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (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.

### Tobramycin 28 mg powder for inhalation, 224 capsules

<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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</thead>
<tbody>
<tr>
<td>10066T</td>
<td>1</td>
<td>..</td>
<td>2459.81</td>
<td>41.00</td>
<td>TOBI podhaler [GO]</td>
</tr>
</tbody>
</table>

#### TOBRAMYCIN

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**4513**

Proven Pseudomonas aeruginosa infection

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have cystic fibrosis, **AND**
- Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules, **AND**
- Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s).

**Population criteria:**
- Patient must be 6 years of age or older.

### Tobramycin 28 mg powder for inhalation, 224 capsules

<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>
<td>10074F</td>
<td>1</td>
<td>2</td>
<td>2459.81</td>
<td>41.00</td>
<td>TOBI podhaler [GO]</td>
</tr>
</tbody>
</table>
### QUINOLONE ANTIBACTERIALS

#### Fluoroquinolones

**CIPROFLOXACIN**

**Authority required**
Respiratory tract infection

**Clinical criteria:**
- The condition must be proven or suspected to be caused by *Pseudomonas aeruginosa*, **AND**
- Patient must be severely immunocompromised.

**CIPROFLOXACIN**

**Authority required**
Bacterial gastroenteritis

**Clinical criteria:**
- Patient must be severely immunocompromised.

**CIPROFLOXACIN**

**Authority required**
Infection

**Clinical criteria:**
- The condition must be proven to be due to *Pseudomonas aeruginosa* resistant to all other oral antimicrobials; OR
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

**CIPROFLOXACIN**

**Authority required**
Bone or joint infection

**Clinical criteria:**
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**CIPROFLOXACIN**

**Authority required**
Epididymo-orchitis

**Clinical criteria:**
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**CIPROFLOXACIN**

**Authority required**
Prostatitis

**Clinical criteria:**
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**CIPROFLOXACIN**

**Authority required**
Perichondritis of the pinna

**Clinical criteria:**
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**CIPROFLOXACIN 500 mg tablet, 14**

<table>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1209P</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* APO-Ciprofloxacin [TX]</td>
<td>* C-Flox 500 [AL]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Cifran [RA]</td>
<td>* Ciprofloxacin AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Ciprofloxacin GH [HQ]</td>
<td>* Ciprofloxacin Sandoz [SZ]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Ciprol 500 [RW]</td>
<td>* Loxip 500 [DO]</td>
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</table>

**CIPROFLOXACIN 750 mg tablet, 14**

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<th>MRVSN $</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1210Q</td>
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<td></td>
<td></td>
<td></td>
<td>* APO-Ciprofloxacin [TX]</td>
<td>* C-Flox 750 [AL]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Ciprofloxacin AN [EA]</td>
<td>* Ciprofloxacin Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Ciprol 750 [RW]</td>
<td>* Loxip 750 [DO]</td>
</tr>
</tbody>
</table>

**CIPROFLOXACIN**

**Authority required**
Respiratory tract infection

**Clinical criteria:**
- The condition must be proven or suspected to be caused by *Pseudomonas aeruginosa*, **AND**
- Patient must be severely immunocompromised.

**CIPROFLOXACIN**

**Authority required**
Bacterial gastroenteritis

**Clinical criteria:**
- Patient must be severely immunocompromised.
• Patient must be severely immunocompromised.

**Authority required**

**Infection**

**Clinical criteria:**
- The condition must be proven to be due to Pseudomonas aeruginosa resistant to all other oral antimicrobials; OR
- The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

**Authority required**

**Bone or joint infection**

**Clinical criteria:**
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

**Epididymo-orchitis**

**Clinical criteria:**
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

**Prostatitis**

**Clinical criteria:**
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

**Perichondritis of the pinna**

**Clinical criteria:**
- The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR
- The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

**Authority required**

**Gonorrhoea**

ciprofloxacin 250 mg tablet, 14

1208N

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer
---|---|---|---|---|---|---
1 | 1 | 15.22 | 16.51 | * APO-Ciprofloxacin [TX] | * C-Flox 250 [AL]
 | 1 | 1 | 1 | * Ciprofloxacin Sandoz [SZ] | * Ciprol 250 [RW]

**NORFLOXACIN**

**Acute bacterial enterocolitis**

**Authority required**

**Complicated urinary tract infection**
	norfloxacin 400 mg tablet, 14

3010K

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer
---|---|---|---|---|---|---
1 | 1 | 15.60 | 16.89 | * APO-Norfloxacin [TX] | * GenRx Norfloxacin [GX]
 | 1 | 1 | 1 | * Nufoxib [AF] | * Roxin [RW]

**OTHER ANTIBACTERIALS**

**Glycopeptide antibacterials**

**VANCOMYCIN**

**Restricted benefit**

**Endocarditis**

**Clinical criteria:**
- The treatment must be for prophylaxis, AND
- Patient must be hypersensitive to penicillin.

vancomycin 1 g injection, 1 vial

2269K

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer
---|---|---|---|---|---|---
1 | 1 | 20.08 | 21.37 | * DBL Vancomycin Hydrochloride [PF] | * Vancomycin Alphapharm [AF]
### vancomycin 500 mg injection, 1 vial

<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>3130R</td>
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<td>*22.10</td>
<td>23.39 Vancomycin Alphapharm [AF]</td>
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</tbody>
</table>

### VANCOMYCIN

**Restricted benefit**
- **Endocarditis**

**Clinical criteria:**
- The treatment must be for prophylaxis, AND
- Patient must be hypersensitive to penicillin.

### vancomycin 1 g injection, 1 vial

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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### vancomycin 500 mg injection, 1 vial

<table>
<thead>
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<th>No of Rpts</th>
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<tr>
<td>3323X</td>
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<td>.</td>
<td>.</td>
<td>*22.10</td>
<td>23.39 Vancomycin Alphapharm [AF]</td>
</tr>
</tbody>
</table>

### VANCOMYCIN

**Restricted benefit**
- **Endophthalmitis**

**Restricted benefit**
- The treatment must be started in a hospital, AND
- The condition must be one in which vancomycin is an appropriate antibiotic.

### vancomycin 1 g injection, 1 vial

<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>2270L</td>
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### vancomycin 500 mg injection, 1 vial

<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>3131T</td>
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<td>*37.24</td>
<td>38.53 Vancomycin Alphapharm [AF]</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.

### sodium fusidate 250 mg tablet, 36

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
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<td>2312Q</td>
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<td>1</td>
<td>.</td>
<td>84.97</td>
<td>41.00 Fucidin [LO]</td>
</tr>
</tbody>
</table>

### FUSIDATE

**Authority required (STREAMLINED)**

**6133**
- **Osteomyelitis**

**Clinical criteria:**
- The condition must be methicillin-resistant staphylococcal aureus (MRSA), AND
- The treatment must be used in combination with other anti-staphylococcal antibiotics.

### sodium fusidate 250 mg tablet, 36

<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>10782L</td>
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<td>1</td>
<td>.</td>
<td>*160.22</td>
<td>41.00 Fucidin [LO]</td>
</tr>
</tbody>
</table>

### Imidazole derivatives

### METRONIDAZOLE

**metronidazole 500 mg suppository, 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>
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<tbody>
<tr>
<td>1642K</td>
<td>†1</td>
<td>.</td>
<td>.</td>
<td>26.58</td>
<td>27.87 Flagyl [SW]</td>
</tr>
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234 Schedule of Pharmaceutical Benefits – December 2020
<table>
<thead>
<tr>
<th>Medicine</th>
<th>Formulation</th>
<th>Quantity</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>Metronidazole 500 mg suppository, 10</td>
<td>5157K</td>
<td>&amp;dquo;</td>
<td>1</td>
<td>..</td>
<td>26.58</td>
<td>27.87</td>
<td>Flagyl [SW]</td>
<td></td>
</tr>
<tr>
<td>Metronidazole 200 mg tablet, 21</td>
<td>1636D</td>
<td>&amp;dquo;</td>
<td>1</td>
<td>1</td>
<td>13.29</td>
<td>14.58</td>
<td>Metrogyl 200 [AF]</td>
<td>Metronide 200 [AV]</td>
</tr>
<tr>
<td>Metronidazole 200 mg tablet, 21</td>
<td>3339R</td>
<td>&amp;dquo;</td>
<td>1</td>
<td>..</td>
<td>13.29</td>
<td>14.58</td>
<td>Flagyl [SW]</td>
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</tr>
<tr>
<td>Metronidazole 200 mg/5 mL oral liquid, 100 mL</td>
<td>1630T</td>
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<td>22.80</td>
<td>24.09</td>
<td>Flagyl S [SW]</td>
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<tr>
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<td>3341W</td>
<td>&amp;dquo;</td>
<td>1</td>
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<td>22.80</td>
<td>24.09</td>
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</tr>
<tr>
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<td>3124K</td>
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<td>1</td>
<td>5</td>
<td>40.25</td>
<td>41.00</td>
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### METRONIDAZOLE

**Restricted benefit**

**Anaerobic infections**

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<tr>
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<th>Formulation</th>
<th>Quantity</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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<tbody>
<tr>
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<td>16.29</td>
<td>Flagyl [SW]</td>
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### NITROFURANTOIN

**Caution** Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.

<table>
<thead>
<tr>
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<th>Formulation</th>
<th>Quantity</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>29.08</td>
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<td>Macrodantin [PF]</td>
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<td>Nitrofurantoin 50 mg capsule, 30</td>
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### METHENAMINE HIP PURRATATE

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### ANTIMYCO TICS FOR SYSTEMIC USE

#### Triazole derivatives

### 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.

**Authority required (STREAMLINED)**
6002
Cryptococcal meningitis

**Authority required (STREAMLINED)**

5978
Cryptococcal meningitis

**Clinical criteria:**
- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

6023
Oropharyngeal candidiasis

**Clinical criteria:**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

5989
Oesophageal candidiasis

**Clinical criteria:**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

6030
Oropharyngeal candidiasis

**Clinical criteria:**
- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

7898
Fungal infection

**Clinical criteria:**
- The condition must be serious or life-threatening.

---

**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.

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**Authority required (STREAMLINED)**

6956
Cryptococcal meningitis

**Authority required (STREAMLINED)**

6978
Cryptococcal meningitis

**Clinical criteria:**
- The treatment must be maintenance therapy, **AND**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

6974
Oropharyngeal candidiasis

**Clinical criteria:**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

6969
Oesophageal candidiasis

**Clinical criteria:**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

6965
Oropharyngeal candidiasis

**Clinical criteria:**
- The treatment must be for prophylaxis, **AND**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

7897
Fungal infection
ANTIINFECTIVES FOR SYSTEMIC USE

General Pharmaceutical Benefits

Clinical criteria:
- The condition must be serious or life-threatening.

**FLUCONAZOLE**

Note Not for use in vulvovaginal 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.

**Clinical criteria:**
- The treatment must be maintenance therapy, AND
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

**6002**
Cryptococcal meningitis

**Authority required (STREAMLINED)**

**5978**
Cryptococcal meningitis

**Clinical criteria:**
- The treatment must be maintenance therapy, AND
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

**6023**
Oropharyngeal candidiasis

**Clinical criteria:**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

**5989**
Oesophageal candidiasis

**Clinical criteria:**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

**6030**
Oropharyngeal candidiasis

**Clinical criteria:**
- The treatment must be for prophylaxis, AND
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

**7898**
Fungal infection

**Clinical criteria:**
- The condition must be serious or life-threatening.

**FLUCONAZOLE**

**Note** Not for use in vulvovaginal 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.

**Authority required (STREAMLINED)**
ANTIINFECTIVES FOR SYSTEMIC USE

6006
Cryptococcal meningitis
Clinical criteria:
• Patient must be unable to take a solid dose form of fluconazole.
Authority required (STREAMLINED)

6045
Cryptococcal meningitis
Clinical criteria:
• The treatment must be maintenance therapy, AND
• Patient must be immunosuppressed, AND
• Patient must be unable to take a solid dose form of fluconazole.
Authority required (STREAMLINED)

6031
Oropharyngeal candidiasis
Clinical criteria:
• Patient must be immunosuppressed, AND
• Patient must be unable to take a solid dose form of fluconazole.
Authority required (STREAMLINED)

6046
Oesophageal candidiasis
Clinical criteria:
• The treatment must be for prophylaxis, AND
• Patient must be immunosuppressed, AND
• Patient must be unable to take a solid dose form of fluconazole.
Authority required (STREAMLINED)

7934
Fungal infection
Clinical criteria:
• The condition must be serious or life-threatening, AND
• Patient must be unable to take a solid dose form of fluconazole.

fluconazole 50 mg/5 mL powder for oral liquid, 35 mL

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
--- --- --- --- --- --- --- ---
5446P 1 .. .. #68.46 41.00 Diflucan [PF]

ITRACONAZOLE

Note Not for use in vulvovaginal candida infections.
Note One capsule of itraconazole 50 mg (Lozanoc) is therapeutically equivalent to one 100 mg capsule of conventional itraconazole (Sporanox). The recommended dose of Lozanoc is therefore half the recommended dose for Sporanox. Lozanoc 50 mg capsules and Sporanox 100 mg capsules are not interchangeable.
Note Not for use in superficial mycoses
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.

Authority required (STREAMLINED)

6022
Systemic aspergillosis
Authority required (STREAMLINED)

6005
Systemic sporotrichosis
Authority required (STREAMLINED)

6057
Systemic histoplasmosis
Authority required (STREAMLINED)

5988
Disseminated pulmonary histoplasmosis infection
Treatment Phase: Treatment and maintenance therapy
Clinical criteria:
• Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).
Authority required (STREAMLINED)
**ANTIINFECTIVES FOR SYSTEMIC USE**

6037
Chronic pulmonary histoplasmosis infection
Treatment Phase: Treatment and maintenance therapy

**Clinical criteria:**
- Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

**Authority required (STREAMLINED)**

6016
Oropharyngeal candidiasis

**Clinical criteria:**
- Patient must be immunosuppressed.

**Authority required (STREAMLINED)**

6035
Oesophageal candidiasis

**Clinical criteria:**
- Patient must be immunosuppressed.

itraconazole 50 mg capsule, 60

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itraconazole 100 mg capsule, 60

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<tbody>
<tr>
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<td></td>
<td></td>
<td></td>
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<td></td>
<td>* APO-Itraconazole [TX]</td>
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<td></td>
<td></td>
<td>* ITRANOX [RW]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Sporanox [JC]</td>
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</table>

**POSACONAZOLE**

**Note** Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

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

**Authority required**

Invasive aspergillosis

**Clinical criteria:**
- Patient must be unable to tolerate alternative therapy; OR
- Patient must have disease refractory to alternative therapy.

**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 funga

posaconazole 100 mg modified release tablet, 24

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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</table>

**VORICONAZOLE**

**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.
**Note** 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.

**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.

### 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.

<table>
<thead>
<tr>
<th>VORICONAZOLE</th>
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</table>

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

### Authority required
Definite or probable invasive aspergillosis

**Clinical criteria:**
- Patient must be immunocompromised.

### Authority required
Serious fungal infections

**Clinical criteria:**
- The condition must be caused by Scedosporium species; OR
- The condition must be caused by Fusarium species.

### Authority required
Serious Candida infections

**Clinical criteria:**
- The condition must be caused by species not susceptible to fluconazole; OR
- The condition must be resistant to fluconazole; OR
- Patient must be unable to tolerate fluconazole.

### Authority required
Serious invasive mycosis infections

**Clinical criteria:**
- The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

---

**voriconazole 40 mg/mL powder for oral liquid, 70 mL**

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**voriconazole 200 mg tablet, 56**

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<tbody>
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**Max Qty**

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**voriconazole 50 mg tablet, 56**

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<tbody>
<tr>
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**Max Qty**

<table>
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**voriconazole 200 mg tablet, 56**

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<tr>
<th>Concentration</th>
<th>Details</th>
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<tbody>
<tr>
<td>200 mg</td>
<td>Tablet, 56</td>
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**Max Qty**

<table>
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<tr>
<th>Quantity</th>
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<tr>
<td>1</td>
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<td>..</td>
<td>827.48</td>
<td>41.00</td>
<td>Vfend [PF]</td>
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</tbody>
</table>

---

**Note** 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.

**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.

### Authority required
Definite or probable invasive aspergillosis

**Clinical criteria:**
- Patient must be immunocompromised.

### Authority required
Serious fungal infections

**Clinical criteria:**
- The condition must be caused by Scedosporium species; OR
- The condition must be caused by Fusarium species.

### Authority required
Serious Candida infections

**Clinical criteria:**
- The condition must be caused by species not susceptible to fluconazole; OR
- The condition must be resistant to fluconazole; OR
- Patient must be unable to tolerate fluconazole.

### Authority required
Serious invasive mycosis infections

**Clinical criteria:**
- The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.
**ANTIINFECTIVES FOR SYSTEMIC USE**

**VORICONAZOLE**

*Note Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.*

**Note Shared Care Model:**

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

**Authority required**

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

**Clinical 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
- The condition must caused by 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 be unable to 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.

**ANTIMYCOBACTERIALS**

**DRUGS FOR TREATMENT OF TUBERCULOSIS**

**Antibiotics**

**RIFAMPICIN**

**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.

**Authority required**

Mycobacterium ulcerans infection (Buruli ulcer)

**Clinical criteria:**

- The treatment must be used in combination with another antibiotic for the treatment of Buruli ulcer.

**rifampicin 150 mg capsule, 10**

<table>
<thead>
<tr>
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<td>295.02</td>
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**rifampicin 150 mg capsule, 100**

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**rifampicin 300 mg capsule, 10**

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### Rifampicin

**Rifampicin 300 mg capsule, 100**

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**Rifampicin 150 mg capsule, 100**

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**Rifampicin 300 mg capsule, 100**

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<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
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<td>116.52</td>
<td>41.00</td>
<td></td>
<td>Rimycin 300 [AF]</td>
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</tbody>
</table>

---

### 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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<tr>
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**Isoniazid 300 mg capsule, 100**

<table>
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### 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

#### 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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<tr>
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**Rifampicin 300 mg capsule, 100**

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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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<td>116.52</td>
<td>41.00</td>
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<td>Rimycin 300 [AF]</td>
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</tbody>
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### Meningococcal Disease

**Clinical criteria:**
- The treatment must be for prophylaxis, **AND**
- Patient must be a carrier of the disease; **OR**
- Patient must be in close contact with people who have the disease.

**Restricted benefit**
- Haemophilus influenzae type B

**Clinical criteria:**
- The treatment must be for prophylaxis, **AND**
- Patient must be in contact with people who have the disease.
### ANTINFECTIVES FOR SYSTEMIC USE

#### General Pharmaceutical Benefits

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
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<tbody>
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### ANTIVIRALS FOR SYSTEMIC USE

#### DIRECT ACTING ANTIVIRALS

### ACICLOVIR

**Note** Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**Authority required** (STREAMLINED)

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>1007B</td>
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### ACICLOVIR

**Note** Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.

**Authority required** (STREAMLINED)

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

**Note** Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**Authority required** (STREAMLINED)

<table>
<thead>
<tr>
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<th>MRVSN $</th>
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### FAMCICLOVIR

**Note** Famiclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

**FAMCICLOVIR**

<table>
<thead>
<tr>
<th>Aciclovir 200 mg tablet, 50</th>
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<td>1555W</td>
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<tr>
<td><strong>Aciclovir APOTEX [TY]</strong></td>
</tr>
<tr>
<td><strong>GenRx Aciclovir [GX]</strong></td>
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### FAMCICLOVIR

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Authority required (STREAMLINED)**

**FAMCICLOVIR**

<table>
<thead>
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<th>Famiclovir 125 mg tablet, 40</th>
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<td>8092X</td>
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</tr>
<tr>
<td><strong>Famiclovir AN [EA]</strong></td>
</tr>
<tr>
<td><strong>Famiclovir [IX]</strong></td>
</tr>
</tbody>
</table>

### FAMCICLOVIR

**Note** Famiclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

**FAMCICLOVIR**

<table>
<thead>
<tr>
<th>Famiclovir 250 mg tablet, 56</th>
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<tr>
<td><strong>Famiclovir-Gen [ED]</strong></td>
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<tr>
<td><strong>Famiclovir [IX]</strong></td>
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**FAMCICLOVIR**

**Note** Famiclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

**FAMCICLOVIR**

<table>
<thead>
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<td><strong>Famiclovir-Gen [ED]</strong></td>
</tr>
</tbody>
</table>
ANTIINFECTIVES FOR SYSTEMIC USE

* Famvir [IX]  * Favic 250 [RW]

### FAMCICLOVIR

Note This drug is only effective if commenced within 72 hours of onset of rash.

Note Famciclovir 500 mg is not PBS-subsidised for chickenpox.

Note Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

Note No applications for repeats will be authorised.

**Authority required (STREAMLINED)**

5943
Herpes zoster

Clinical criteria:
- Patient must be immunocompromised, AND
- The treatment must be administered within 72 hours of the onset of the rash.

**famciclovir 500 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<td>* Auro-Famciclovir 500 [DO]</td>
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<td></td>
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<td></td>
<td>* Famciclovir AN [EA]</td>
<td>* Famciclovir [IX]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Famiclovir GA [ED]</td>
<td>* Famiclovir generichealth 500 [GQ]</td>
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<td></td>
<td></td>
<td>* Famiclovir [IX]</td>
<td>* Favic 500 [RW]</td>
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</tbody>
</table>

### FAMCICLOVIR

Note Famciclovir 500 mg is not PBS-subsidised for chickenpox.

Note Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

**Authority required (STREAMLINED)**

5954
Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

Clinical criteria:
- Patient must be immunocompromised.
- Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Authority required (STREAMLINED)**

5947
Recurrent moderate to severe oral or labial herpes

Treatment Phase: Episodic treatment

Clinical criteria:
- Patient must have HIV infection, AND
- Patient must have CD4 cell count of less than 500 million per litre.
- Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Authority required (STREAMLINED)**

5948
Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

Clinical criteria:
- Patient must have HIV infection, AND
- Patient must have CD4 cell counts of less than 150 million per litre.
- Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**Authority required (STREAMLINED)**

5949
Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

Clinical criteria:
- Patient must have HIV infection, AND
- Patient must present with other opportunistic infections or AIDS defining tumours.
- Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

**famciclovir 500 mg tablet, 56**

<table>
<thead>
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<td>* Auro-Famciclovir 500 [DO]</td>
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<td></td>
<td>* Ezovir [AF]</td>
<td>* Famiclovir AN [EA]</td>
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<td>* Famiclovir generichealth 500 [GQ]</td>
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<td>* Famiclovir [IX]</td>
<td>* Famiclovir 500 [RW]</td>
</tr>
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</table>
ANTIINFECTIVES FOR SYSTEMIC USE

### VALACICLOVIR

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

<table>
<thead>
<tr>
<th>Authority required (STREAMLINED)</th>
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<tr>
<td>Treatment Phase: Suppressive therapy</td>
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<tr>
<td>Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.</td>
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#### valaciclovir 500 mg tablet, 30

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<th>Max Qty Packs</th>
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#### valaciclovir 500 mg tablet, 30

<table>
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<td>* Zelitrex [RF]</td>
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#### valaciclovir 500 mg tablet, 10

<table>
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<td></td>
<td>* Valaciclovir AN [EA]</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>* Valaciclovir APOTEX [GX]</td>
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<td>* Valaciclovir Sandoz [SZ]</td>
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</tbody>
</table>

### VALACICLOVIR

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Authority required (STREAMLINED)**

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

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

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

<table>
<thead>
<tr>
<th>Authority required (STREAMLINED)</th>
</tr>
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<tbody>
<tr>
<td>5960 Initial moderate to severe genital herpes</td>
</tr>
<tr>
<td>Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.</td>
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#### valaciclovir 500 mg tablet, 10

<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>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>8133C</td>
<td>2</td>
<td>*21.52</td>
<td>22.81</td>
<td></td>
<td>* APO-Valaciclovir [TX]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Valaciclovir AN [EA]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Valaciclovir APOTEX [GX]</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Valaciclovir Sandoz [SZ]</td>
<td></td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td>2.26</td>
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</tr>
</tbody>
</table>

### VALACICLOVIR

**Note** This drug is only effective if commenced within 72 hours of onset of rash.

**Note** Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

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

<table>
<thead>
<tr>
<th>Authority required (STREAMLINED)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5962 Herpes zoster</td>
</tr>
<tr>
<td>Clinical criteria:</td>
</tr>
<tr>
<td>• The treatment must be administered within 72 hours of the onset of the rash.</td>
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</table>

<table>
<thead>
<tr>
<th>Authority required (STREAMLINED)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5968 Herpes zoster ophthalmicus</td>
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Schedule of Pharmaceutical Benefits – December 2020
**ANTIINFECTIVES FOR SYSTEMIC USE**

**General Pharmaceutical Benefits**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>APO-Valaciclovir [TX]</td>
<td>Vaclovir [AF]</td>
</tr>
<tr>
<td>Valaciclovir AN [EA]</td>
<td>Valaciclovir APOTEX [GX]</td>
</tr>
<tr>
<td>Valaciclovir generichealth [GQ]</td>
<td>Valaciclovir RBX [RA]</td>
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<tr>
<td>Valaciclovir Sandoz [SZ]</td>
<td>Valtacor 500 [CR]</td>
</tr>
<tr>
<td>Zelitrex [RF]</td>
<td></td>
</tr>
</tbody>
</table>

**Antivirals for treatment of HCV infections**

- **ELBASVIR + GRAZOPREVIR**
  - **Note** No increase in the maximum quantity or number of units may be authorised.
  - **Note** No increase in the maximum number of repeats may be authorised.
  - **Note** Special Pricing Arrangements apply.

  **Authority required**
  Chronic hepatitis C infection

  **Clinical criteria:**
  - Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
  - Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
  - The treatment must be limited to a maximum duration of 16 weeks.

- **ELBASVIR + GRAZOPREVIR**
  - **Note** No increase in the maximum quantity or number of units may be authorised.
  - **Note** No increase in the maximum number of repeats may be authorised.
  - **Note** Special Pricing Arrangements apply.

  **Authority required**
  Chronic hepatitis C infection

  **Clinical criteria:**
  - Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
  - Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
  - The treatment must be limited to a maximum duration of 12 weeks.

- **GLECAPREVIR + PIBRENTASVIR**
  - **Note** No increase in the maximum quantity or number of units may be authorised.
  - **Note** No increase in the maximum number of repeats may be authorised.
  - **Note** Special Pricing Arrangements apply.

  **Authority required**
  Chronic hepatitis C infection

  **Clinical criteria:**
  - Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
  - Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
  - The treatment must be limited to a maximum duration of 16 weeks.

  The application must include details of the prior treatment regimen containing an NS5A inhibitor.

- **GLECAPREVIR + PIBRENTASVIR**
  - **Note** No increase in the maximum quantity or number of units may be authorised.
  - **Note** No increase in the maximum number of repeats may be authorised.
  - **Note** Special Pricing Arrangements apply.

  **Authority required**
  Chronic hepatitis C infection

  **Clinical criteria:**
  - Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**

---

**General Pharmaceutical Benefits** 247
ANTIINFECTIVES FOR SYSTEMIC USE

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 8 weeks.

glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84

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

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

Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

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

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

Note Special Pricing Arrangements apply.
ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

<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>10670N</td>
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<td>5</td>
<td>..</td>
<td>12676.96</td>
<td>Harvoni [GI]</td>
</tr>
</tbody>
</table>

**RIBAVIRIN**

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

**Authority required**
Chronic hepatitis C infection

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**Population criteria:**
- 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.

ribavirin 600 mg tablet, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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ribavirin 400 mg tablet, 28

<table>
<thead>
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<tr>
<td>10647J</td>
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<td>2</td>
<td>..</td>
<td>323.13</td>
<td>Ibavyr [IX]</td>
</tr>
</tbody>
</table>

**RIBAVIRIN**

**Caution** Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

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

**Authority required**
Chronic hepatitis C infection

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 24 weeks.

**Population criteria:**
- 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.

ribavirin 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>
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<tr>
<td>10666J</td>
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<td>481.18</td>
<td>Ibavyr [IX]</td>
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ribavirin 400 mg tablet, 28

<table>
<thead>
<tr>
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<td>Ibavyr [IX]</td>
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</tbody>
</table>

**SOFOSBUVIR + VELPATASVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic hepatitis C infection

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>11147Q</td>
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<td>2</td>
<td>..</td>
<td>12676.96</td>
<td>Epclusa [GI]</td>
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</tbody>
</table>
**SOFSOBUVIR + VELPATASVIR + VOXILAPREVIR**

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

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

*Note* Special Pricing Arrangements apply.

**Authority required**
- Chronic hepatitis C infection

**Clinical criteria:**
- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
- The treatment must be limited to a maximum duration of 12 weeks.

The application must include details of the prior treatment regimen containing an NS5A inhibitor.

**sofosbuvir 400 mg + velpatasvir 100 mg + voxilaprevir 100 mg tablet, 28**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tr>
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<td>12676.96</td>
<td>41.00</td>
<td>Vosevi [SI]</td>
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</tbody>
</table>

**TENOFOVIR DISOPROXIL + EMTRICITABINE**

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

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

*Note* Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg tablet, tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg tablet, and tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg tablet are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**
- 7580

Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection

**Clinical criteria:**
- The treatment must be for patients at medium to high risk of HIV infection, as defined by the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) Guidelines, AND
- Patient must have a negative HIV test result prior to treatment with PBS-subsidised therapy with this drug.

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

**tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tbody>
<tr>
<td>1</td>
<td>2</td>
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<td>111.47</td>
<td>41.00</td>
<td>* Tenofovir Disoproxil Emtricitabine Mylan 300/200 [AF]</td>
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</table>

**tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30**

<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>2</td>
<td>..</td>
<td>111.47</td>
<td>41.00</td>
<td>* Tenofovir/Emtricitabine 300/200 APOTEX [TX]</td>
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**tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30**

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<tbody>
<tr>
<td>1</td>
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<td>111.47</td>
<td>41.00</td>
<td>* Tenofovir EMT GH [GQ]</td>
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**VACCINES**

**BACTERIAL VACCINES**

**Tetanus vaccines**

**DIPHTHERIA + TETANUS VACCINE**

*Note* For immunisation of adults and children aged greater than or equal to 8 years.

**diphtheria 2 units + tetanus 20 units vaccine injection, 5 x 0.5 mL syringes**

<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>70.46</td>
<td>41.00</td>
<td>ADT Booster [CS]</td>
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**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

**ANTINEOPLASTIC AGENTS**

**ALKYLATING AGENTS**

**Nitrogen mustard analogues**
### Chlorambucil

<table>
<thead>
<tr>
<th>Chlorambucil 2 mg tablet, 25</th>
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<tr>
<td>1163F</td>
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<td>Max Qty Packs</td>
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### Cyclophosphamide

<table>
<thead>
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<th>Cyclophosphamide 50 mg tablet, 50</th>
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<td>Max Qty Packs</td>
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### Melphalan

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<td>Max Qty Packs</td>
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#### Alkyl sulfonates

### Busulfan

<table>
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<td>1128J</td>
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<tr>
<td>Max Qty Packs</td>
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<tr>
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</table>

#### Nitrosoureas

### Carmustine

**Note** Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.

#### Restricted benefit

**Glioblastoma multiforme**

**Clinical criteria:**
- The condition must be suspected or confirmed at the time of initial surgery.

<table>
<thead>
<tr>
<th>Carmustine 7.7 mg implant, 8</th>
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<tbody>
<tr>
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Other alkylating agents

### Temozolomide

#### Temozolomide 250 mg capsule, 5

<table>
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<th>Temozolomide 250 mg capsule, 5</th>
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<td>Max Qty Packs</td>
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#### Temozolomide 5 mg capsule, 5

<table>
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#### Temozolomide 180 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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<td>1</td>
</tr>
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<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
### Temozolomide

**Note** Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.

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

#### Restricted benefit

Malignant glioblastoma multiforme

**Treatment criteria:**
- Patient must be undergoing concomitant radiotherapy.

### Methotrexate

#### Methotrexate 5 mg/2 mL injection, 5 x 2 mL vials

<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>
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<td>40.87</td>
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<td>DBL</td>
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**DBL Methotrexate [PF]**

#### 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>17.85</td>
<td>19.14</td>
<td>Methoblastin [PF]</td>
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</tr>
</tbody>
</table>

**Methotrexate**

**Restricted benefit**

Patients requiring doses greater than 20 mg per week
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- **METHOTREXATE**
  
  Note For item codes 2395C and 1818Q, pharmaceutical benefits that have the form injection 50 mg in 2 mL are equivalent for the purposes of substitution.

  methotrexate 50 mg/2 mL injection, 2 mL vial
  
<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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  methotrexate 50 mg/2 mL injection, 5 x 2 mL vials
  
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- **FLU Darabine**

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- **MER CAPTOPURINE**

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- **TI OGUANINE**

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- **CAPECITABINE**

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- **TRI FLURIDINE + TI PIRACIL**

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

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

  Note Special Pricing Arrangements apply.

  Authority required (STREAMLINED)

  10309
  Metastatic colorectal cancer
  Treatment Phase: Initial treatment
  Clinical criteria:
  - Patient must have a WHO performance status of 1 or less, **AND**
  - Patient must have previously received treatment with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapies, an anti-vascular endothelial growth factor (anti-VEGF) agent and an anti-epidermal growth factor receptor (anti-EGFR) agent for this condition; **OR**
  - Patient must not be a suitable candidate for treatment with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapies, an anti-VEGF agent and an anti-EGFR agent for this condition, **AND**
  - The treatment must be the sole PBS-subsidised therapy for this condition.
  The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.

  Authority required (STREAMLINED)

  8183
  Metastatic colorectal cancer
  Treatment Phase: Continuing treatment
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

**Clinical criteria:**
- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

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**TRIFLURIDINE + TIPIRACIL**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10252**
Metastatic (Stage IV) adenocarcinoma of the stomach or gastro-oesophageal junction
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must have previously received at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum and either a taxane or irinotecan, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

The patient’s WHO performance status and body weight must be documented in the patient’s medical records at the time the treatment cycle is initiated.

**Authority required (STREAMLINED)**

**10310**
Metastatic (Stage IV) adenocarcinoma of the stomach or gastro-oesophageal junction
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop progressive disease whilst receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

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**PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS**

*Vinca alkaloids and analogues*

**VINORELBINE**

**Authority required**
Advanced breast cancer

**Clinical criteria:**
- Patient must have failed standard prior therapy, which includes an anthracycline.

**Authority required**
Locally advanced or metastatic non-small cell lung cancer

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**Podophyllotoxin derivatives**
**ETOPOSIDE**

etoposide 100 mg capsule, 10

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etoposide 50 mg capsule, 20

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**OTHER ANTINEOPLASTIC AGENTS**

**Monoclonal antibodies**

**RITUXIMAB**

*Authority required (STREAMLINED)*

7400

Previously untreated or relapsed/refractory CD20 positive lymphoid cancer

Treatment Phase: Induction or re-induction therapy

**Clinical criteria:**

- The treatment must be for induction or re-induction for CD20 positive lymphoma; OR
- The treatment must be for induction or re-induction for CD20 positive chronic lymphocytic leukaemia; OR
- The treatment must be for induction or consolidation for CD20 positive acute lymphoblastic leukaemia, **AND**
- The treatment must be in combination with chemotherapy, **AND**
- Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab.

No more than 8 doses in total as per course of treatment will be allowed for lymphoma or chronic lymphocytic leukaemia.

No more than 12 doses in total as per course of treatment will be allowed for acute lymphoblastic leukaemia for induction course (including consolidation course).

**rituximab 1.4 g/11.7 mL injection, 11.7 mL vial**

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**RITUXIMAB**

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

*Authority required (STREAMLINED)*

6011

Relapsed or refractory Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current Authority application, **AND**
- Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.

**rituximab 1.4 g/11.7 mL injection, 11.7 mL vial**

<table>
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**RITUXIMAB**

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

*Authority required (STREAMLINED)*

7399

Previously untreated or Relapsed/refractory CD20 positive acute lymphoblastic leukaemia

Treatment Phase: Maintenance therapy

**Clinical criteria:**

- The treatment must be maintenance therapy, **AND**
- The treatment must be in combination with chemotherapy, **AND**
- Patient must be in complete remission, **AND**
- Patient must not receive more than 6 doses in total under this restriction.

**rituximab 1.4 g/11.7 mL injection, 11.7 mL vial**

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</table>
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

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**RITUXIMAB**

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

### Authority required (STREAMLINED)

**10227**

Relapsed or refractory follicular B-cell non-Hodgkin’s lymphoma

**Clinical criteria:**
- The treatment must be for re-induction treatment purposes only, **AND**
- The condition must have relapsed or be refractory to treatment, **AND**
- Patient must not receive more than 4 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 3 doses of subcutaneous rituximab under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 4 doses in total.

**Rituximab 1.4 g/11.7 mL injection, 11.7 mL vial**

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**RITUXIMAB**

*Note* A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

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

### Authority required (STREAMLINED)

**6161**

Stage III or IV CD20 positive follicular B-cell non-Hodgkin’s lymphoma

**Clinical criteria:**
- Patient must have demonstrated a partial or complete response to induction treatment with either R-CHOP or R-CVP regimens for previously untreated follicular B-cell Non-Hodgkin’s lymphoma, received immediately prior to this current Authority application, **AND**
- Patient must not have received bendamustine induction therapy, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.

**Rituximab 1.4 g/11.7 mL injection, 11.7 mL vial**

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**TRASTUZUMAB**

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

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

### Authority required (STREAMLINED)

**10212**

Early HER2 positive breast cancer

**Clinical criteria:**
- Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant), **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR
- Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

**Trastuzumab 600 mg/5 mL injection, 5 mL vial**

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**TRASTUZUMAB**

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

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

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

### Authority required (STREAMLINED)

**9353**
Metastatic (Stage IV) HER2 positive breast cancer
Treatment Phase: Initial treatment
Clinical criteria:
- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- The treatment must not be in combination with nab-paclitaxel, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.
Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

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

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

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

**Authority required (STREAMLINED)**

9462
Metastatic (Stage IV) HER2 positive breast cancer
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

**trastuzumab 600 mg/5 mL injection, 5 mL vial**

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**Protein kinase inhibitors**

**ABEMACICLIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Locally advanced or metastatic breast cancer
Treatment Phase: Initial treatment
Clinical criteria:
- Patient must not have previously been treated with an aromatase inhibitor for advanced or metastatic breast cancer, **AND**
- Patient must not have previously been treated with palbociclib or ribociclib; **OR**
- Patient must have developed an intolerance to palbociclib or ribociclib of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with palbociclib or ribociclib.
Population criteria:
- Patient must not be premenopausal.

**Authority required**

Locally advanced or metastatic breast cancer
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with palbociclib or ribociclib.
Population criteria:
### Antineoplastic and Immunomodulating Agents

#### Abemaciclib 50 mg tablet, 56

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#### Abemaciclib 100 mg tablet, 56

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### Acalabrutinib

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

**Note**
Special Pricing Arrangements apply.

**Note**
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

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**Authority required**

Relapsed or refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be considered unsuitable for treatment or retreatment with a purine analogue, **AND**
- Patient must have not received treatment with another Bruton’s tyrosine kinase (BTK) inhibitor for any line of treatment of CLL/SLL (untreated or relapsed/refractory disease); **OR**
- Patient must have developed intolerance to another Bruton’s tyrosine kinase (BTK) inhibitor of a severity necessitating permanent treatment withdrawal when being treated for relapsed or refractory CLL/SLL.

A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following:

- a) Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;  
- b) Age is 70 years or older;  
- c) Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylation agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen;  
- d) History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;  
- e) Evidence of one or more 17p chromosomal deletions demonstrated by a Medical Benefits Schedule listed test.

**Authority required**

Relapsed or refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

**Treatment Phase: Continuing treatment of relapsed or refractory CLL/SLL**

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Authority required**

Relapsed or refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

**Treatment Phase: Grandfather treatment (initial treatment in a patient commenced on non-PBS-subsidised treatment)**

**Clinical criteria:**
- Patient must have previously received non-PBS-subsidised treatment with this drug for relapsed or refractory CLL/SLL prior to 1 September 2020, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a WHO performance status of 1 or less prior to starting non-PBS-subsidised treatment with this drug, **AND**
- Patient must have been considered unsuitable for treatment or retreatment with a purine analogue prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be considered unsuitable for treatment or retreatment with a purine analogue, **AND**
• Patient must not have received treatment with another Bruton’s tyrosine kinase (BTK) inhibitor for any line of treatment of CLL/SLL (untreated or relapsed/refractory disease) prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
• Patient must have developed intolerance to another Bruton’s tyrosine kinase (BTK) inhibitor of a severity necessitating permanent treatment withdrawal when being treated for relapsed or refractory CLL/SLL prior to initiating non-PBS-subsidised treatment with this drug for this condition, AND
• Patient must not have developed disease progression while receiving treatment with this drug for this condition.

A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following being met prior to commencing non-PBS-subsidised treatment with this drug for this condition:

- a) Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;
- b) Age is 70 years or older;
- c) Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with a medical history of smoking and/or a history of renal impairment.
- d) History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;
- e) Evidence of one or more 17p chromosomal deletions demonstrated by a Medical Benefits Schedule listed test.

Note: 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: This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

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### AFATINIB

**Note** Special Pricing Arrangements apply.

#### Authority required

**Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)**

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**

- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

#### afatinib 20 mg tablet, 28

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### AFATINIB

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

**Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Clinical criteria:
  - Patients must have previously received either: one line of chemotherapy, or at least two lines of chemotherapy.
  - Treatment with afatinib must be continued as monotherapy.
  - The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC.
  - Patient must have evidence of a WHO performance status of 1 or less.
  - Evidence of one or more 17p chromosomal deletions demonstrated by a Medical Benefits Schedule listed test.
  - 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.
  - 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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  - 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.
  - Evidencing of one or more 17p chromosomal deletions demonstrated by a Medical Benefits Schedule listed test.
The treatment must be as monotherapy, **AND**

Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition.

**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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**afatinib 20 mg tablet, 28**

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**ALECTINIB**

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

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

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**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 have a WHO performance status of 2 or less.

**Population criteria:**

Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

**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 received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**alectinib 150 mg capsule, 4 x 56**

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**AXITINIB**

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

- **Complete response (CR)** is disappearance of all target lesions.
- **Partial response (PR)** is a 30% decrease in the sum of the longest diameter of target lesions.
- **Progressive disease (PD)** is a 20% increase in the sum of the longest diameter of target lesions.
- **Stable disease (SD)** is small changes that do not meet above criteria.

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

7433

Stage IV clear cell variant renal cell carcinoma (RCC)

**Treatment Phase:** Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have received an initial 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.

Prescribers may request an increased maximum quantity sufficient to provide up to one month’s supply for patients who require dose adjustment.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

axitinib 1 mg tablet, 28

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axitinib 5 mg tablet, 28

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**AXITINIB**

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

**Note** Special Pricing Arrangements apply.

**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**

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 prior 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.

Prescribers may request an increased maximum quantity sufficient to provide up to one month’s supply for patients who require dose adjustment.

binimetinib 15 mg tablet, 84

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General Authority required (STREAMLINED)

10306
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously been issued with an authority prescription for this drug, AND
- Patient must be receiving PBS-subsidised encorafenib concomitantly for this condition, AND
- Patient must have stable or responding disease.

Binimetinib 15 mg tablet, 84
11961M

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**BRIGATINIB**

Note: No increase in the maximum quantity or number of units may be authorised.
Note: No increase in the maximum number of repeats may be authorised.
Note: Special Pricing Arrangements apply.

Authority required
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 received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Brigatinib 180 mg tablet, 28
11984R

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Brigatinib 90 mg tablet, 28
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Brigatinib 30 mg tablet, 28
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**BRIGATINIB**

Caution: Careful monitoring of patients is required due to risk of developing pulmonary adverse events observed in patients within the first seven days of treatment with this drug. Patients must be instructed to report any new or worsening respiratory symptoms.
Note: No increase in the maximum quantity or number of units may be authorised.
Note: No increase in the maximum number of repeats may be authorised.
Note: Special Pricing Arrangements apply.

Authority required
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment
Clinical criteria:
- The treatment must be as monotherapy, AND
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, AND
- Patient must have a WHO performance status of 2 or less.
Population criteria:
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

Brigatinib 90 mg tablet [7] & brigatinib 180 mg tablet [21], 1 pack
11976H

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**CABOZANTINIB**

Note: No increase in the maximum number of repeats may be authorised.
Note: Special Pricing Arrangements apply.
Note: Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
- Stable disease (SD) is small changes that do not meet above criteria.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

General Pharmaceutical Benefits

Authority required (STREAMLINED)

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 prior 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.

Cabozantinib 20 mg tablet, 30

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**Cabozantinib**

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

Note: Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
- Stable disease (SD) is small changes that do not meet above criteria.

Note: Special Pricing Arrangements apply.

Authority required (STREAMLINED)

Stage IIIB (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 have a WHO performance status of 2 or less.

Population criteria:

Authorised

Ceritinib

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

Note: Special Pricing Arrangements apply.
• Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Clinical criteria:**
- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

### ceritinib 150 mg capsule, 3 x 50

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**Note**

- No increase in the maximum quantity or number of units may be authorised.
- No increase in the maximum number of repeats may be authorised.
- Special Pricing Arrangements apply.

### COBIMETINIB

**Note**

- A patient who has had progressive disease when treated with this drug is no longer eligible for 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.

**Authority required (STREAMLINED)**

10033

Unresectable Stage III or Stage IV malignant melanoma

**Clinical criteria:**
- Patient must be receiving PBS subsidised vemurafenib concomitantly for this condition.

### cobimetinib 20 mg tablet, 63

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**Note**

- Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

6803

Unresectable Stage III or Stage IV malignant melanoma

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised vemurafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

### CRIZOTINIB

**Note**

- Special Pricing Arrangements apply.

**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 have a WHO performance status of 2 or less.

**Population criteria:**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Non-Small-Cell Lung Cancer Authority Application - Supporting Information Form.

**Note**

- Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available...
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**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 develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**Note**
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**CRIZOTINIB**

- **Note** Special Pricing Arrangements apply.

**Authority required**
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment

**Clinical criteria:**
- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, **AND**
- Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; OR
- Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Non-Small-Cell Lung Cancer Authority Application - Supporting Information Form.

**Note**
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**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 received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

**Note**
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
**DABRAFENIB**

- **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.

**Authority required [STREAMLINED]**

- **10157** Unresectable Stage III or Stage IV malignant melanoma
  - **Treatment Phase:** Initial treatment
  - **Clinical criteria:**
    - The condition must be positive for a BRAF V600 mutation, **AND**
    - The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; **OR**
    - Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal, **AND**
    - Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage III, IIIC or IIIID melanoma, **AND**
    - Patient must have a WHO performance status of 2 or less.

**dabrafenib 75 mg capsule, 120**

- **2846T**
  - Max Qty Packs: 1
  - No of Rpts: 3
  - Premium $: 7540.36
  - DPMQ $: 7540.36
  - MRVSN $: 41.00
  - Brand Name and Manufacturer: Tafinlar [NV]

**dabrafenib 50 mg capsule, 120**

- **2963Y**
  - Max Qty Packs: 1
  - No of Rpts: 3
  - Premium $: 5085.90
  - DPMQ $: 5085.90
  - MRVSN $: 41.00
  - Brand Name and Manufacturer: Tafinlar [NV]

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**DABRAFENIB**

- **Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Authority required [STREAMLINED]**

- **6013** Unresectable Stage III or Stage IV malignant melanoma
  - **Treatment Phase:** Continuing treatment
  - **Clinical criteria:**
    - Patient must have previously been issued with an authority prescription for this drug, **AND**
    - Patient must have stable or responding disease.

**dabrafenib 75 mg capsule, 120**

- **10003L**
  - Max Qty Packs: 1
  - No of Rpts: 5
  - Premium $: 7540.36
  - DPMQ $: 7540.36
  - MRVSN $: 41.00
  - Brand Name and Manufacturer: Tafinlar [NV]

**dabrafenib 50 mg capsule, 120**

- **2954L**
  - Max Qty Packs: 1
  - No of Rpts: 5
  - Premium $: 5085.90
  - DPMQ $: 5085.90
  - MRVSN $: 41.00
  - Brand Name and Manufacturer: Tafinlar [NV]

---

**DABRAFENIB**

- **Note** No increase in the maximum quantity or number of units may be authorised.
- **Note** No increase in the maximum number of repeats may be authorised.
- **Note** Special Pricing Arrangements apply.

**Authority required**

- Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma
Treatment Phase: Initial treatment

Clinical criteria:
- The treatment must be adjuvant to complete surgical resection, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition, **AND**
- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- The treatment must commence within 12 weeks of complete resection, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**Authority required**

Resected Stage IIIb, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously been issued with an authority prescription for trametinib and dabrafenib concomitantly for adjuvant treatment following complete surgical resection, **AND**
- Patient must not have experienced disease recurrence, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**Authority required**

Resected Stage IIIb, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Grandfather treatment

Clinical criteria:
- Patient must have previously received non-PBS subsidised drug for adjuvant treatment following complete surgical resection prior to 1 November 2019, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have a WHO performance status of 1 or less prior to starting non-PBS treatment with this drug, **AND**
- Patient must not have evidence of recurrence, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition, **AND**
- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- Patient must have commenced non-PBS-subsidised treatment within 12 weeks of complete surgical resection, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

### dabrafenib 75 mg capsule, 120

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### DASATINIB

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesilate 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 as 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
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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. 6. Definitions of loss of response. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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

Authority required
Chronic Myeloid Leukaemia (CML)
Treatment Phase: Initial treatment
Clinical criteria:
• Patient must not have failed PBS-subsidised first line treatment with this drug for this condition, AND
• Patient must have failed an adequate trial of PBS-subsidised first line treatment with imatinib for this condition; OR
• Patient must have failed an adequate trial of PBS-subsidised first line treatment with nilotinib for this condition; OR
• Patient must have experienced intolerance, not a failure of response, to PBS-subsidised second line treatment with nilotinib for this condition, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of imatinib or nilotinib is defined as:(i) Lack of response to initial imatinib or nilotinib therapy, defined as either:- failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or nilotinib for patients initially treated in chronic phase; or- failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or nilotinib; OR(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or nilotinib therapy; OR(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or(3) Peripheral basophils greater than or equal to 20%; or(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin over 4 weeks; or(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); ORB Blast crisis is defined as either:(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or(2) Extramedullary involvement other than spleen and liver; OR(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia. Patients should be commenced on a dose of dasatinib at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:(a) a completed authority prescription form; and(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and(c) a signed patient acknowledgement; and(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and(e) where there has been a loss of response to imatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement

Authority required
Chronic Myeloid Leukaemia (CML)
Treatment Phase: Continuing treatment
Clinical criteria:
• Patient must have received initial PBS- subsidised second line treatment with this drug for this condition; OR
• Patient must have experienced intolerance, not a failure to respond, to PBS-subsidised second line treatment with nilotinib for this condition, AND
• Patient must have demonstrated a major cytogenetic response in the preceding 18 months and thereafter at 12 monthly intervals; OR
• Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% in the preceding 18 months and thereafter at 12 monthly intervals, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.

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 need be provided; or (b) a peripheral blood level of BCR-ABL of less than 1% on the international scale 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 need be provided.

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### DASATINIB

#### Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, 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 First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, 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 to respond

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

For imatinib mesilate:

First continuing applications may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

For dasatinib or nilotinib:

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 may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 to respond, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, 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.

3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, 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).

4. 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.

5. Definitions of loss of response

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Philadelphia positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.
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.

**Authority required**

**Chronic Myeloid Leukaemia (CML)**

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- The condition must be a primary diagnosis, **AND**
- The condition must be in the chronic phase, **AND**
- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL tyrosine kinase, **AND**
- The treatment must be for first line therapy for this condition, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first line therapy for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

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 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; 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.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

**Chronic Myeloid Leukaemia (CML)**

**Treatment Phase: First continuing treatment**

**Clinical criteria:**

- The condition must be in the chronic phase, **AND**
- Patient must have received initial PBS-subsidised first line treatment with this drug for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenic response; **OR**
- Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

First continuing 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. a major cytogenic 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].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 may be directed to Services 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 and other relevant documentation as applicable) is available
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Chronic Myeloid Leukaemia (CML)

**Treatment Phase: Subsequent continuing treatment**

**Clinical criteria:**
- The condition must be in the chronic phase, **AND**
- Patient must have received the First continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have maintained a major cytogenic response; **OR**
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**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).

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1416M

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**DASATINIB**

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

**Authority required**

Acute lymphoblastic leukaemia

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have failed treatment with chemotherapy, **AND**
- Patient must have failed treatment with imatinib, **AND**
- Patient must have failed an allogeneic haemopoietic stem cell transplantation if applicable.

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 expressing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The 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 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.

Note Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesilate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Acute lymphoblastic leukaemia
Treatment Phase: Initial treatment

Clinical criteria:
- Patient must be newly diagnosed, AND
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, AND
- The treatment must be for induction and consolidation therapy, AND
- The treatment must be in combination with chemotherapy or corticosteroids, AND
- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition.

The 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 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).

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

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HOBART TAS 7001

Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Authority required
Acute lymphoblastic leukaemia
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with imatinib as a first-line therapy for this condition, AND

- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, AND
- The treatment must be for maintenance of first complete remission, AND
- The treatment must be in combination with chemotherapy or corticosteroids.

Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting.

**Note** Any queries concerning the arrangements to prescribe this drug beyond 24 months may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

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**ENCORAFENIB**

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

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

**Note** Special Pricing Arrangements apply.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

10271

Unresectable Stage III or Stage IV malignant melanoma

**Clinical criteria:**

- The condition must be positive for a BRAF V600 mutation, AND
- The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; OR
- Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal, AND
- Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIIB, IIIC or IIID melanoma, AND
- Patient must have a WHO performance status of 2 or less.

encorafenib 50 mg capsule, 28

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**ENCORAFENIB**

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

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

**Note** Special Pricing Arrangements apply.

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

6013
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously been issued with an authority prescription for this drug, AND
- Patient must have stable or responding disease.

**encorafenib 50 mg capsule, 28**

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**ENTRECTINIB**

Note Special Pricing Arrangements apply.

**Authority required**
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment
Clinical criteria:
- The treatment must be as monotherapy, AND
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, AND
- Patient must have a WHO performance status of 2 or less, AND
- Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; OR
- Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal, AND
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

The authority application must be made in writing and must include:
1) a completed authority prescription form; and
2) a completed Non-Small-Cell Lung Cancer Authority Application - Supporting Information Form.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**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 received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have developed disease progression while being treated with this drug for this condition.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Grandfather treatment
Clinical criteria:
- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2020, AND
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, AND
- The treatment must be as monotherapy, AND
- Patient must have had a WHO performance status of 2 or less prior to initiating non-PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have developed disease progression while being treated with this drug for this condition, AND
• Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition prior to initiating non-PBS subsidised treatment with this drug for this condition; OR
• Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal prior to initiating non-PBS subsidised treatment with this drug for this condition; AND
• Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing prior to initiating non-PBS subsidised treatment with this drug for this condition.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Non-Small-Cell Lung Cancer Authority Application - Supporting Information Form.

A patient 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 This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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### ERLOTINIB

**Authority required**
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- The treatment must be as monotherapy, 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.

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**erlotinib 150 mg tablet, 30**
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### ERLOTINIB

**Authority required (STREAMLINED)**
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- The treatment must be as monotherapy, AND
- Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014, AND
- Patient must not have progressive disease.

**Population criteria:**
### General

- Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR
- Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

### ERLOTINIB

**Authority required (STREAMLINED)**

7446

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 received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have progressive disease.

**Population criteria:**
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

### EVEROLIMUS

**Authority required (STREAMLINED)**

7431

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 received an initial authority prescription for this drug for this condition, **AND**
- Patient must have demonstrated a response to prior treatment.
### Clinical criteria:
- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be a candidate for curative surgical resection.

**everolimus 2.5 mg tablet, 30**

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**EVEROLIMUS**

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

**Authority required**

Refractory seizures associated with tuberous sclerosis complex

**Clinical criteria:**
- Patient must have a confirmed diagnosis of tuberous sclerosis complex (TSC), **AND**
- Patient must be experiencing a minimum of two partial-onset seizures per week, **AND**
- The condition must have failed to be controlled satisfactorily at stable doses of at least two anti-epileptic drugs, **AND**
- The treatment must be in combination with at least one anti-epileptic drug, **AND**
- Patient must not be a candidate for curative surgery.

**Population criteria:**
- Patient must be at least 2 years of age.

**everolimus 2 mg dispersible tablet, 30**

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**everolimus 3 mg dispersible tablet, 30**

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**EVEROLIMUS**

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

**Authority required (STREAMLINED)**

8262

Refractory seizures associated with tuberous sclerosis complex

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have maintained a response to the PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with at least one anti-epileptic drug, **AND**
- Patient must not be a candidate for curative surgery.

**everolimus 2 mg dispersible tablet, 30**

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**EVEROLIMUS**

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

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

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

**Treatment Phase: Continuing treatment**
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

### everolimus 10 mg tablet, 30

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### EVEROLIMUS

**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 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.

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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**

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.
EVEROLIMUS

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note 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 progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST)
    following prior 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.

everolimus 10 mg tablet, 30

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GERIFINIB

Authority required (STREAMLINED)
7447
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 received an initial authority prescription for this drug for this condition, AND
  • Patient must not have progressive disease.
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

### gefitinib 250 mg tablet, 30

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**Authority required**

- **Stage IIB (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 have a WHO performance status of 0 or 1, **AND**
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); **OR**
- Patient must have evidence of one or more 17p chromosomal deletions demonstrated by fluorescence in situ hybridisation (FISH). **AND**

**Population criteria:**

- Patient must develop intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal. **AND**

**Special Pricing Arrangements apply.**

### gefitinib 250 mg tablet, 30

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**Authority required**

- Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)
- **Treatment Phase: Initial treatment**

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- Patient must have previously received PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) for any line of treatment of CLL/SLL (untreated or relapsed/refractory disease); **OR**
- Patient must have developed intolerance to another Bruton's tyrosine kinase (BTK) inhibitor of a severity necessitating permanent treatment withdrawal when being treated for relapsed or refractory CLL/SLL, **AND**
- Patient must be unsuitable for treatment or retreatment with a purine analogue. A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following:
  a) Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;
  b) Age is 70 years or older;
  c) Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with a purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylating agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen;
  d) History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;
  e) Evidence of one or more 17p chromosomal deletions demonstrated by fluorescence in situ hybridisation (FISH). **AND**

**Authority required**

- Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)
- **Treatment Phase: Continuing treatment**

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition. **AND**

### ibritinib 140 mg capsule, 90

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### Ibrutinib

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

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

**Note**
Special Pricing Arrangements apply.

**Note**
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

#### Authority required

**Mantle cell lymphoma**

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

**Authority required**

**Mantle cell lymphoma**

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**ibrutinib 140 mg capsule, 120**

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### Imatinib

**Note**

Authority applications for increased quantities/ repeats (where relevant) 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).

#### Authority required (STREAMLINED)

**9278**

**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.

**imatinib 100 mg tablet, 60**

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**imatinib 400 mg tablet, 30**

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### Imatinib

**Note**

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

#### Authority required

**Gastrointestinal stromal tumour**

**Treatment Phase:** Initial treatment

**Clinical criteria:**
- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), **AND**
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST, **AND**
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, **AND**
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

**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.
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 must be documented in the patient’s medical records. The pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection, which must not be more than 3 months prior to treatment initiation must be recorded in the patient’s medical records.

### IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

**Authority required**
- Myelodysplastic or myeloproliferative disorder
- Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by standard karyotyping; OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by fluorescence in situ hybridization (FISH); OR
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement by PDGFRB fusion gene transcript, AND
- Patient must have previously failed an adequate trial of conventional therapy with cytotoxic agents; OR
- Patient must have previously failed an adequate trial of conventional therapy with etoposide; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxyurea and etoposide, AND
- The treatment must not exceed a maximum dose of 400 mg per day.

A bone marrow biopsy report demonstrating the presence of a myelodysplastic or myeloproliferative disorder, a pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement and details of the prior trialled therapy and the response must be documented in the patient’s medical records.

### imatinib 100 mg tablet, 60

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### IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

**Authority required**
- Aggressive systemic mastocytosis with eosinophilia
- Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, AND
- Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; OR
- Patient must have previously failed an adequate trial of conventional therapy with hydroxyurea, AND
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFR fusion gene, a bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a full blood examination report demonstrating eosinophilia must be documented in the patient’s medical records.

The details of symptomatic organ involvement requiring treatment, including radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient’s medical records.

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**IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

**Authority required**
Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

**Clinical criteria:**
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRα fusion gene, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFRα fusion gene, a full examination report and details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient’s medical records.

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**IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

**Authority required**
Dermatofibrosarcoma protuberans

**Clinical criteria:**
- The condition must be unresectable; **OR**
- The condition must be locally recurrent; **OR**
- The condition must be metastatic, **AND**
- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient’s medical records.

### imatinib 400 mg tablet, 30

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**IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

**Authority required**
Myelodysplastic or myeloproliferative disorder

**Clinical criteria:**
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFRα) gene re-arrangement by standard karyotyping; **OR**
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFRα) gene re-arrangement by fluorescence in situ hybridization (FISH); **OR**
- Patient must have confirmed evidence of a platelet-derived growth factor receptor (PDGFRα) gene re-arrangement by PDGFRB fusion gene transcript, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with cytarabine; **OR**
- Patient must have previously failed an adequate trial of conventional therapy with etoposide; **OR**
- Patient must have previously failed an adequate trial of conventional therapy with hydroxycarbamide (hydroxyurea), **AND**
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- The treatment must not exceed a maximum dose of 400 mg per day.
- A bone marrow biopsy report demonstrating the presence of a myelodysplastic or myeloproliferative disorder, a pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement and details of the prior trialled therapy and the response must be documented in the patient's medical records.

**IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

**Authority required**

Aggressive systemic mastocytosis with eosinophilia

**Treatment Phase:** Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- Patient must have previously failed an adequate trial of conventional therapy with corticosteroids; **OR**
- Patient must have previously failed an adequate trial of conventional therapy with hydroxyurea, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFR fusion gene, a bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a full blood examination report demonstrating eosinophilia must be documented in the patient's medical records.

The details of symptomatic organ involvement requiring treatment, including radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

**IMATINIB**

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**Authority required**

Chronic eosinophilic leukaemia or Hypereosinophilic syndrome

**Treatment Phase:** Initial treatment

**Clinical criteria:**

- Patient must have confirmed evidence of carrying the FIP1L1-PDGFR fusion gene, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A pathology report confirming the presence of the FIP1L1-PDGFR fusion gene, a bone marrow biopsy report and/or other organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate must be documented in the patient's medical records.

**IMATINIB**

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

Treatment Phase: Initial treatment

Clinical criteria:
- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, AND
- The treatment must not exceed a maximum dose of 800 mg per day.

Details of unresectable tumour or site of the local recurrence or site(s) of metastatic disease must be documented in the patient's medical records.

IMATINIB

Note: Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

IMATINIB

Dermatofibrosarcoma protuberans

Clinical criteria:
- The condition must be unresectable; OR
- The condition must be locally recurrent; OR
- The condition must be metastatic, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must have demonstrated a response to the PBS-subsidised treatment, AND
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, AND
- The treatment must not exceed a maximum dose of 800 mg per day.

Evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

IMATINIB

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

Myelodysplastic or myeloproliferative disorder

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The condition must be PDGFRB fusion gene-positive, AND
- Patient must have achieved and maintained a complete haematological response, AND
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, AND
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.
• IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

Authority required (STREAMLINED)
9243
Myelodysplastic or myeloproliferative disorder
Treatment Phase: Continuing treatment
Clinical criteria:
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
• The condition must be PDGFRB fusion gene-positive, AND
• Patient must have achieved and maintained a complete haematological response, AND
• The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, AND
• The treatment must not exceed a maximum dose of 400 mg per day.
A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

• IMATINIB

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

Authority required (STREAMLINED)
9296
Chronic eosinophilic leukaemia or Hypereosinophilic syndrome
Treatment Phase: Continuing treatment
Clinical criteria:
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
• Patient must have achieved and maintained a complete haematological response, AND
• The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, AND
• The treatment must not exceed a maximum dose of 400 mg per day.
A full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count and a statement that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRα fusion gene, **AND**
- Patient must have achieved and maintained a complete haematological response, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

### IMATINIB

#### Note
Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

#### Authority required (STREAMLINED)

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IMATINIB

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

Authority required (STREAMLINED)

Malignant gastrointestinal stromal tumour
Treatment Phase: Continuing treatment

Clinical criteria:
- The condition must be metastatic; OR
- The condition must be unresectable, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be given at a dose not exceeding 600 mg per day.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.

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.)

imatinib 100 mg tablet, 60

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imatinib 400 mg tablet, 30

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IMATINIB

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

Authority required (STREAMLINED)

Aggressive systemic mastocytosis with eosinophilia
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must have confirmed evidence of carrying the FIP1L1-PDGFRα fusion gene, AND
- Patient must have achieved and maintained a complete haematological response, AND
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, AND
- The treatment must not exceed a maximum dose of 400 mg per day.

A full blood examination report which demonstrates a complete haematological response and evidence that the disease has not progressed on imatinib therapy must be documented in the patient's medical records.

imatinib 400 mg tablet, 30

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IMATINIB

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

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

Authority required

Malignant gastrointestinal stromal tumour
Treatment Phase: Initial Treatment

Clinical criteria:
- The condition must be metastatic; OR
- The condition must be unresectable, AND
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, AND
• The treatment must be commenced at a dose not exceeding 400 mg per day, AND
• The treatment must not exceed 3 months under this restriction. Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period. 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.)

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 must be documented in the patient's medical records. Details 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 must be documented in the patient's medical records.

Where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence must be documented in the patient's medical records.

### IMATINIB

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephoning to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** 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 mesilate, 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 First-line treatment** From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, 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 to respond.

2. **Continuing First-line treatment**

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

For imatinib mesilate:

First continuing applications may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

For dasatinib or nilotinib:

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 may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 to respond, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, 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.

3. **Authority approval requirements**

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, 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 16 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).

4. **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.

5. **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.

**Authority required (STREAMLINED)**

**9295**

Chronic Myeloid Leukaemia (CML)

**Treatment Phase:** Subsequent continuing

**Clinical criteria:**

- The condition must be in the chronic phase of chronic myeloid leukaemia, AND
- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, AND
- Patient must have maintained a major cytogenetic response; OR
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, AND
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Imatinib 400 mg tablet, 30**

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Note: The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesilate, 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 First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, 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 to respond
- 2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

For imatinib mesilate:
- First continuing applications may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

For dasatinib or nilotinib:
- 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 may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

During ongoing tyrosine kinase inhibitor 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 to respond, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, 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.

3. Authority approval requirements: Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, 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).

4. Definitions of response
A major cytogenic 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 cytogenic response.

5. Definitions of loss of response
Loss of a previously documented major cytogenic 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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**Authority required (STREAMLINED)**

**9295**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing

**Clinical criteria:**
- The condition must be in the chronic phase of chronic myeloid leukaemia, **AND**
- Patient must have received initial continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have maintained a major cytogenic response; **OR**
- Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

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**IMATINIB**

**Note**
Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

**Note**
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 mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alpha therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. **Initial First-line treatment**

   - From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, 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 to respond.

2. **Continuing First-line treatment**

   - Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

   - For imatinib mesilate:
     - First continuing applications may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
     - For dasatinib or nilotinib:
       - 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 may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

   - During continuing therapy beyond the initial 18 month treatment period, switching approved first-line agents may only occur for reason of intolerance. Where there is failure to respond, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, 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.

3. **Authority approval requirements**
   - Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib...
nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, 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).

4. 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.

5. 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.

Authority required
Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:
- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the chronic phase of chronic myeloid leukaemia, **AND**
- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL tyrosine kinase, **AND**
- The treatment must be for first line therapy for this condition, **AND**
- Patient must not have previously experienced a failure to respond to the PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

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 mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

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 must be documented in the patient’s medical records.

Authority required
Chronic Myeloid Leukaemia (CML)

Treatment Phase: First Continuing

Clinical criteria:
- The condition must be in the chronic phase of chronic myeloid leukaemia, **AND**
- Patient must have received initial PBS-subsidised treatment with this drug as a first line therapy for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition; **OR**
- Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, **AND**
- Patient must have demonstrated a major cytogenic response; **OR**
- Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, **AND**
- The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenetic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.
IMATINIB

Note Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

Note 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 mesilate, 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 First-line treatment

From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, 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 to respond.

2. Continuing First-line treatment

Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

For imatinib mesilate:

First continuing applications may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

For dasatinib or nilotinib:

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 may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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 to respond, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, 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.

3. Authority approval requirements

Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, 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).

4. 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.

5. 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.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a primary diagnosis of chronic myeloid leukaemia, AND
- The condition must be in the chronic phase of chronic myeloid leukaemia, AND
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase, AND
- The treatment must be for first line therapy for this condition, AND
- Patient must not have previously experienced a failure to respond to the PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with nilotinib as a first line therapy for this condition, AND

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• The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.

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 mesilate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesilate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

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 must be documented in the patient’s medical records.

Authority required
Chronic Myeloid Leukaemia (CML)
Treatment Phase: First Continuing

Clinical criteria:
• The condition must be in the chronic phase of chronic myeloid leukaemia, AND
• Patient must have received initial PBS-subsidised treatment with this drug as a first line therapy for this condition; OR
• Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR
• Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with nilotinib as a first line therapy for this condition, AND
• Patient must have demonstrated a major cytogenic response; OR
• The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.

A major cytogenic response [see Note explaining requirements] or a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements] must be documented in the patient's medical records.

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**IMATINIB**

Note
Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

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

Note
Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Authority required
Acute lymphoblastic leukaemia
Treatment Phase: Initial treatment

Clinical criteria:
• Patient must be newly diagnosed, AND
• The condition must be expressing the Philadelphia chromosome; OR
• The condition must have the transcript BCR-ABL, AND
• The treatment must be for induction and consolidation therapy, AND
• The treatment must be in combination with chemotherapy or corticosteroids, AND
• Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
• Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia 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 must be documented in the patient's medical records.

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**IMATINIB**

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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).

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have a primary diagnosis of chronic myeloid leukaemia, AND
- The condition must be in the accelerated phase, AND
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

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).

**Authority required**

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must have a primary diagnosis of chronic myeloid leukaemia, AND
- The condition must be in the blast phase, AND
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

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.

imatinib 100 mg tablet, 60

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**IMATINIB**

Note Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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).

**Authority required**

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must be newly diagnosed, AND
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, AND
- The treatment must be for induction and consolidation therapy, AND
- The treatment must be in combination with chemotherapy or corticosteroids, AND
• Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
• Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition.

A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia 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 must be documented in the patient’s medical records.

### Imatinib 100 mg Tablet, 60

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### Imatinib

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

**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).

### Authority required

Chronic Myeloid Leukaemia (CML)

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the accelerated phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

**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 great increase in size below the left costal margin over 4 weeks; or
5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

### Authority required

Chronic Myeloid Leukaemia (CML)

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- Patient must have a primary diagnosis of chronic myeloid leukaemia, **AND**
- The condition must be in the blast phase, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

**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.

### Imatinib 400 mg Tablet, 30

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### Imatinib 400 mg Capsule, 30

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### Imatinib

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

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

**Note** Authority applications for increased quantities/ repeats (where relevant) 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).
General Pharmaceutical Benefits

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Authority required (STREAMLINED)**

**9207**
Acute lymphoblastic leukaemia
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for maintenance of first complete remission, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids.

Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting.

**imatinib 400 mg tablet, 30**

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**imatinib 400 mg capsule, 30**

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**IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

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

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

**Authority required (STREAMLINED)**

**9207**
Acute lymphoblastic leukaemia
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition, **AND**
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL, **AND**
- The treatment must be for maintenance of first complete remission, **AND**
- The treatment must be in combination with chemotherapy or corticosteroids.

Dasatinib and imatinib are available with a lifetime maximum of 24 months for continuing treatment for patients with acute lymphoblastic leukaemia reimbursed through the PBS in this treatment setting.

**imatinib 100 mg tablet, 60**

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**imatinib 100 mg capsule, 60**

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**IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 400 mg and imatinib capsule 400 mg are equivalent for the purposes of substitution.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

**Authority required (STREAMLINED)**

**10026**
Chronic Myeloid Leukaemia (CML)
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The condition must be in the accelerated phase, AND
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

**Authority required (STREAMLINED)**

**10048**
Chronic Myeloid Leukaemia (CML)
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The condition must be in the blast phase, AND
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

**imatinib 400 mg tablet, 30**

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**imatinib 400 mg capsule, 30**

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**IMATINIB**

**Note** Pharmaceutical benefits that have the form imatinib tablet 100 mg and imatinib capsule 100 mg are equivalent for the purposes of substitution.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

**Authority required (STREAMLINED)**

**10026**
Chronic Myeloid Leukaemia (CML)
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The condition must be in the accelerated phase, AND
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

**Authority required (STREAMLINED)**

**10048**
Chronic Myeloid Leukaemia (CML)
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The condition must be in the blast phase, AND
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase.

**imatinib 100 mg tablet, 60**

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**LAPATINIB**

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

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

**Authority required (STREAMLINED)**

**9360**
Metastatic (Stage IV) HER2 positive breast cancer
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have received an initial authority prescription for this drug for this condition, AND
• The treatment must be in combination with capecitabine, **AND**
• Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
• The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
• The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The treatment must not exceed a lifetime total of one continuous course.

### LAPATINIB

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

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

**Clinical criteria:**

• Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
• The treatment must be in combination with capecitabine, **AND**
• Patient must have received prior therapy with a taxane for at least 3 cycles; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; OR
• Patient must have developed intolerance to treatment with a taxane of a severity necessitating permanent treatment withdrawal; and experienced disease progression during or within 6 months of completing treatment with pertuzumab and trastuzumab in combination; OR
• Patient must have experienced disease progression following treatment with trastuzumab emtansine in whom disease had relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab; OR
• Patient must have experienced disease relapsed during or within 6 months of completing prior adjuvant therapy with trastuzumab, **AND**
• The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, **AND**
• The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes:
(i) details of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH); and
(ii) date of last treatment with a taxane and total number of cycles; or
(iii) dates of treatment with trastuzumab and pertuzumab; or
(iv) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab; or
(v) date of demonstration of progression during or within 6 months of completing treatment with trastuzumab.

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.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.

### LENVATINIB

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

**Note** Special Pricing Arrangements apply.
**Authority required (STREAMLINED)**

10991
Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma
Treatment Phase: Initial treatment

Clinical criteria:
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not be suitable for transarterial chemoembolisation, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have Child Pugh class A, **AND**
- The condition must be untreated with systemic therapy; OR
- Patient must have developed intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal.

**Authority required (STREAMLINED)**

8584
Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma
Treatment Phase: Continuing treatment

Clinical criteria:
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition.

**LENVATINIB**

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

Note: Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

6604
Locally advanced or metastatic differentiated thyroid cancer
Treatment Phase: Initial treatment

Clinical criteria:
- The condition must be refractory to radioactive iodine, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have symptomatic progressive disease prior to treatment; OR
- Patient must have progressive disease at critical sites with a high risk of morbidity or mortality where local control cannot be achieved by other measures, **AND**
- Patient must have thyroid stimulating hormone adequately repressed, **AND**
- Patient must be one in whom surgery is inappropriate, **AND**
- Patient must not be a candidate for radiotherapy with curative intent, **AND**
- Patient must have a WHO performance status of 2 or less.

Radioactive iodine refractory is defined as:
- a lesion without iodine uptake on a radioactive iodine (RAI) scan; or
- having received a cumulative RAI dose of greater than or equal to 600 mCi; or
- progression within 12 months of a single RAI treatment; or
- progression after two RAI treatments administered within 12 months of each other.

**Authority required (STREAMLINED)**

6578
Locally advanced or metastatic differentiated thyroid cancer
Treatment Phase: Continuing treatment

Clinical criteria:
- The condition must be refractory to radioactive iodine, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST).

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.
LORLATINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required
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 have a WHO performance status of 2 or less, AND
- The condition must have progressed following treatment with an anaplastic lymphoma kinase (ALK) inhibitor other than crizotinib.

Population criteria:
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement.

Authority required
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 received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Authority required
Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Grandfather treatment
Clinical criteria:
- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2020, AND
- 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 have had a WHO performance status of 2 or less prior to initiating non-PBS-subsidised treatment, AND
- The condition must have progressed following treatment with an ALK inhibitor other than crizotinib prior to commencement of non-PBS-subsidised treatment with this drug for this PBS indication, AND
- Patient must not have progressive disease while receiving treatment with this drug for this condition.

Population criteria:
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement.

A patient 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.

NILOTINIB

Authority required
Chronic Myeloid Leukaemia (CML)
Treatment Phase: Initial treatment
Clinical criteria:
- The condition must be a primary diagnosis, AND
- The condition must be in the chronic phase, AND
- The condition must be expressing the Philadelphia chromosome; OR
- The condition must have the transcript BCR-ABL tyrosine kinase, AND
- The treatment must be for first line therapy for this condition, AND
General

Antineoplastic and Immunomodulating Agents

- Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first line therapy for this condition; OR
- Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first line therapy for this condition; AND
- The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition. AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

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 include:(1) a completed authority prescription form; and(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form; 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. 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 mesilate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alpha therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial First-line treatment From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesilate, 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 to respond. 2. Continuing First-line treatment - Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

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 may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). 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 to respond, switching may only occur through application for prescription of second-line agents. Where a patient has previously received PBS-subsidised treatment with imatinib mesilate, 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.

3. Authority approval requirements. Response criteria to initial first-line treatment with imatinib mesilate, dasatinib or nilotinib: For the purposes of assessing response to PBS-subsidised treatment with imatinib mesilate, 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 mesilate, 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).

4. 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.

5. Definitions of loss of response. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9625
HOBART TAS 7001

Authority required
Chronic Myeloid Leukaemia (CML)
Treatment Phase: First continuing treatment
Clinical criteria:
• The condition must be in the chronic phase, **AND**
• Patient must have received initial PBS-subsidised first line treatment with this drug for this condition; **OR**
• Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; **OR**
• Patient must have experienced intolerance, not a failure to respond, to first continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition, **AND**
• Patient must have demonstrated a major cytogenic response; **OR**
• Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, **AND**
• The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
• The treatment must be the sole PBS-subsidised therapy for this condition.

First continuing 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) 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]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided.

**Authority required**

Chronic Myeloid Leukaemia (CML)

**Treatment Phase:** Subsequent continuing treatment

**Clinical criteria:**

• The condition must be in the chronic phase, **AND**
• Patient must have received the First continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; **OR**
• Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with imatinib as a first line therapy for this condition; **OR**
• Patient must have experienced intolerance, not a failure to respond, to subsequent continuing PBS-subsidised treatment with dasatinib as a first line therapy for this condition, **AND**
• Patient must have maintained a major cytogenic response; **OR**
• Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, **AND**
• The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, **AND**
• The treatment must be the sole PBS-subsidised therapy for this condition.

Subsequent authority applications for continuing therapy with this drug may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**nilotinib 150 mg capsule, 120**

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**NILOTINIB**

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

Prescribing information (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 this drug should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001

**Authority required**

Chronic Myeloid Leukaemia (CML)

**Treatment Phase:** Initial treatment

**Clinical criteria:**

• The condition must be in the chronic phase; **OR**
• The condition must be in the accelerated phase, **AND**
• Patient must have failed an adequate trial of PBS-subsidised first line treatment with imatinib for this condition; **OR**
• Patient must have failed an adequate trial of PBS-subsidised first line treatment with dasatinib for this condition, **AND**
• The treatment must be the sole PBS-subsidised therapy for this condition.

Failure of an adequate trial of imatinib or dasatinib is defined as:(i) Lack of response to initial imatinib or dasatinib therapy, defined as either:- failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib for patients initially treated in chronic phase; or- failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or- failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib; OR(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or...
dasatinib therapy; OR(iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia. Accelerated phase is defined by the presence of 1 or more of the following:(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or(3) Peripheral basophils greater than or equal to 20%; or(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy. Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals. Applications for authorisation must be in writing and must include:(a) a completed authority prescription form; and(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and(c) a signed patient acknowledgement; and(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and(e) where there has been a loss of response to imatinib or dasatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesilate 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 TKI therapy: 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 1 month of the commencement of treatment with dasatinib or nilotinib (patient has responded to PBS-subsidised treatment with 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. 6. 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.

**Authority required**

**Chronic Myeloid Leukaemia (CML)**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a major cytogenetic response to nilotinib in the preceding 18 months and thereafter at 12 monthly intervals; **OR**
- Patient must have achieved a peripheral blood level of BCR-ABL of less than 1% to nilotinib in the preceding 18 months and thereafter at 12 monthly intervals, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

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.

nilotinib 200 mg capsule, 120
9171Q

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### NINTEDANIB

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 1 - new patient

**Clinical criteria:**
- The condition must be diagnosed through a multidisciplinary team, **AND**
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, **AND**
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, **AND**
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, **AND**
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, **AND**
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition.

**Treatment criteria:**
- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.

Patient must not have an acute respiratory infection at the time of FVC testing.

Application for authorisation of initial treatment must be in writing and must include:
- a) a completed authority prescription form; and
- b) a completed IPF Authority Application Supporting Information Form; and
- c) a signed patient acknowledgement.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Initial treatment 2 - change or re-commencement of treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition.

**Treatment criteria:**
- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Idiopathic pulmonary fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition.
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

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### Treatment criteria:

- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

**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).

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### OSIMERTINIB

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

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

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**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 received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

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### osimertinib 40 mg tablet, 30

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### OSIMERTINIB

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)  
Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The condition must have progressed on or after prior epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapy as first line treatment for this condition, **AND**
- Patient must have evidence of EGFR T790M mutation in tumour material at the point of progression on or after first line EGFR TKI treatment.

Authority applications for initial treatment must be made in writing and must include:

- (a) a completed authority prescription form;
- (b) a completed Non-Small-Cell Lung Cancer Authority Application - Supporting Information Form;
- (c) details of the pathology report from an Approved Pathology Authority confirming evidence of EGFR T790M mutation in tumour material while on or after first line EGFR TKI treatment; and
- (d) date of commencement of first line EGFR TKI treatment and date of progression whilst on or after first line EGFR TKI treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9626  
HOBART TAS 7001

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**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 received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Note** Application for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**PALBOCICLIB**

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

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

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

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**Authority required**
Locally advanced or metastatic breast cancer

**TREATMENT PHASE: INITIAL TREATMENT**

**Clinical criteria:**
- Patient must not have previously been treated with an aromatase inhibitor for advanced or metastatic breast cancer, **AND**
- Patient must not have previously been treated with abemaciclib or ribociclib; OR
- Patient must have developed an intolerance to abemaciclib or ribociclib of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with abemaciclib or ribociclib.

**Population criteria:**
- Patient must not be premenopausal.

**Authority required**
Locally advanced or metastatic breast cancer

**TREATMENT PHASE: CONTINUING TREATMENT**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with 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 in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with abemaciclib or ribociclib.

**Population criteria:**
- Patient must not be premenopausal.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

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**PAZOPANIB**

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions. Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions. Stable disease (SD) is small changes that do not meet above criteria.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7422
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:
- Patient must have received an initial 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
- Patient must require dose adjustment, AND
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor 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.

Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

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### PAZOPANIB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

9247
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;
- Ewing's tumour/primitive neuroectodermal tumour;
- dermatofibromatosis sarcoma protuberans;
- inflammatory myofibroblastic sarcoma;
- malignant mesothelioma;
- mixed mesodermal tumour of the uterus.

### pazopanib 200 mg tablet, 90

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### PAZOPANIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
- Complete response (CR) is disappearance of all target lesions.
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- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
- Stable disease (SD) is small changes that do not meet above criteria.

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

Note No increase in the maximum number of repeats may be authorised.
Antineoplastic and Immunomodulating Agents

Note: Special Pricing Arrangements apply.

Authority required (STREAMLINED)
7458
Advanced (unresectable and/or metastatic) soft tissue sarcoma
Treatment Phase: Continuing treatment beyond 3 months
Clinical criteria:
- Patient must have received an initial 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.

Pazopanib 200 mg tablet, 90

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PAZOPANIB

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- Stable disease (SD) is small changes that do not meet above criteria.

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

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

Note: Special Pricing Arrangements apply.

Authority required (STREAMLINED)
7459
Advanced (unresectable and/or metastatic) soft tissue sarcoma
Treatment Phase: Continuing treatment beyond 3 months
Clinical criteria:
- Patient must have received an initial 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
- Patient must require dose adjustment, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Pazopanib 200 mg tablet, 30

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PAZOPANIB

Note: Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
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Note: No increase in the maximum quantity or number of units may be authorised.

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

Note: Special Pricing Arrangements apply.

Authority required (STREAMLINED)
7423
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Continuing treatment beyond 3 months
Clinical criteria:
- Patient must have received an initial 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 tyrosine kinase inhibitor 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.
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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**Pazopanib**

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

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

*Note* Special Pricing Arrangements apply.

*Note* Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised pazopanib.

*Note* Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

**Authority required (STREAMLINED)**

9281

Stage IV clear cell variant renal cell carcinoma (RCC)

**Clinical criteria:**

- The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), **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.

**pazopanib 200 mg tablet, 90**

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**Ponatinib**

*Authority required*

Acute lymphoblastic leukaemia

**Clinical criteria:**

- The condition must be expressing the Philadelphia chromosome; **OR**
- The condition must have the transcript BCR-ABL, **AND**
- Patient must have failed prior treatment with PBS-subsidised dasatinib for this condition; **OR**
- Patient must have developed intolerance to PBS-subsidised dasatinib of a severity requiring treatment withdrawal.

Failure of treatment with dasatinib is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with PBS-subsidised dasatinib for this condition; or
2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by PBS-subsidised dasatinib for this condition; or
3. Rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

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; **OR** rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Acute Lymphoblastic Leukaemia ponatinib PBS Authority Application - Supporting Information Form; and
3. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, 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; or
4. pathology reports documenting rising levels of BCR-ABL1 transcript on two consecutive occasions in a patient in complete remission while being treated with PBS-subsidised dasatinib for this condition. The date of the relevant pathology report(s) need(s) to be provided.

*Note* Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Authority required
Acute lymphoblastic leukaemia
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition.

Note
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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• PONATINIB

Authority required
Acute lymphoblastic leukaemia
Treatment Phase: Initial treatment

Clinical criteria:
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must be expressing the T315I mutation, AND
- Patient must have failed treatment with chemotherapy, with or without another tyrosine kinase inhibitor, AND
- Patient must have failed allogeneic haemopoietic stem cell transplantation (where appropriate).

Failure of treatment is defined as either:
1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy, with or without another tyrosine kinase inhibitor;
2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy, with or without another tyrosine kinase inhibitor;
3. 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 authority application must be made in writing and must include:
1. a completed authority prescription form; and
2. a completed Acute Lymphoblastic Leukaemia - ponatinib Initial PBS authority application form; and
3. a signed patient acknowledgement; and
4. 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; and evidence of the T315I mutation. The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided.

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
Note
Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Applications for authority to prescribe should be forwarded to:
Department of Human Services

Complex Drugs

Reply Paid 9826

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• PONATINIB

Note
Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib or ponatinib at any one time and must not be receiving concomitant interferon alfa therapy.

Note 1. Continuing treatment

First continuing applications are to be written, 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.

Subsequent authority applications for continuing therapy may be made by telephoning the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

2. Authority approval requirements.

Response criteria to treatment with ponatinib:

For the purposes of assessing response to PBS-subsidised treatment with ponatinib, 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 conducted within 18 months of the commencement of treatment with ponatinib (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 first continuing treatment with this drug).

Thereafter, at no greater than 12 month intervals a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% must be sustained to receive subsequent continuing treatments with this drug.

3. 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).


Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Philadelphia positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor 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.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

• The treatment must be the sole PBS-subsidised therapy for this condition, AND
• Patient must have failed an adequate trial of dasatinib; OR
• Patient must have developed intolerance to dasatinib of a severity necessitating permanent treatment withdrawal. AND
• Patient must have failed an adequate trial of nilotinib; OR
• Patient must have developed intolerance to nilotinib of a severity necessitating permanent treatment withdrawal; OR
• Patient must not be eligible for PBS-subsidised treatment with nilotinib because the patient has a blast crisis.

Failure of an adequate trial of dasatinib or nilotinib is defined as:

1. Lack of response to dasatinib or nilotinib therapy, defined as either:
   (i) failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib or nilotinib; or
   (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
(iii) 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 dasatinib or nilotinib; OR
2. 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 dasatinib or nilotinib therapy; OR
3. 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 dasatinib or nilotinib therapy; OR
4. Development of accelerated phase or blast crisis in a patient previously prescribed dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR
5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis 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).

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.

The authority application must be made in writing and must include:
1. a completed authority prescription form; and
2. a completed Chronic Myeloid Leukaemia - ponatinib Initial PBS authority application form; and
3. 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
4. where there has been a loss of response to dasatinib 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.

Up to a maximum of 18 months of treatment may be authorised under this initial restriction.

Note: Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Chronic Myeloid Leukaemia (CML)
Treatment Phase: Initial treatment

Clinical criteria:
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must be expressing the T315I mutation, AND
- Patient must have failed an adequate trial of imatinib; OR
- Patient must have failed an adequate trial of dasatinib; OR
- Patient must have failed an adequate trial of nilotinib.

Failure of an adequate trial of imatinib or dasatinib or nilotinib is defined as:
1. Lack of response to imatinib or dasatinib or nilotinib therapy, defined as either:
   (i) failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib or nilotinib; or
   (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
   (iii) 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 nilotinib; OR
2. 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 or nilotinib therapy; OR
3. 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 or nilotinib therapy; OR
4. Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR
5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during imatinib or dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis 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).

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.

The authority application must be made in writing and must include:
1. a completed authority prescription form; and
2. a completed Chronic Myeloid Leukaemia - ponatinib Initial PBS authority application form; and
3. 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 and evidence of the T315I mutation. (The date of the relevant pathology report(s) need to be provided); and
4. where there has been a loss of response to imatinib or dasatinib 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.

Up to a maximum of 18 months of treatment may be authorised under this initial restriction.

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

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

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001
• Patient must have maintained a major cytogenic response at 12 month intervals; OR
• Patient must have maintained a peripheral blood level of BCR-ABL of less than 1% at 12 month intervals.

### ponatinib 15 mg tablet, 60

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- **RIBOCICLIB**

  **Caution** QT interval monitoring is required for patients treated with this drug.

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

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

  **Note** Special Pricing Arrangements apply.

### Authority required

Locally advanced or metastatic breast cancer

**Clinical criteria:**

- Patient must not have previously been treated with an aromatase inhibitor for advanced or metastatic breast cancer, **AND**
- Patient must not have previously been treated with abemaciclib or palbociclib; **OR**
- Patient must have developed an intolerance to abemaciclib or palbociclib of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with abemaciclib or palbociclib, **AND**
- Patient must require dosage reduction requiring a pack of 21 tablets.

**Population criteria:**

- Patient must not be premenopausal.

### Authority required

 Locally advanced or metastatic breast cancer

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must be in combination with anastrozole or letrozole, **AND**
- The treatment must not be in combination with abemaciclib or palbociclib, **AND**
- Patient must require dosage reduction requiring a pack of 21 tablets.

**Population criteria:**

- Patient must not be premenopausal.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

### ribociclib 200 mg tablet, 21

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- **RIBOCICLIB**

  **Caution** QT interval monitoring is required for patients treated with this drug.

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

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

  **Note** Special Pricing Arrangements apply.

### Authority required

Locally advanced or metastatic breast cancer

**Clinical criteria:**

- Patient must not have previously been treated with an aromatase inhibitor for advanced or metastatic breast cancer, **AND**
- Patient must not have previously been treated with abemaciclib or palbociclib; **OR**
• Patient must have developed an intolerance to abemaciclib or palbociclib of a severity necessitating permanent treatment withdrawal, AND
• The condition must be hormone receptor positive, AND
• The condition must be human epidermal growth factor receptor 2 (HER2) negative, AND
• The condition must be inoperable, AND
• Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, AND
• The treatment must be in combination with anastrozole or letrozole, AND
• The treatment must not be in combination with abemaciclib or palbociclib.

**Population criteria:**
• Patient must not be premenopausal.

**Authority required**
Locally advanced or metastatic breast cancer
Treatment Phase: Continuing treatment

**Clinical criteria:**
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
• Patient must not develop disease progression while receiving treatment with this drug for this condition, AND
• Patient must have stable or responding disease, AND
• The treatment must be in combination with anastrozole or letrozole, AND
• The treatment must not be in combination with abemaciclib or palbociclib.

**Population criteria:**
• Patient must not be premenopausal.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

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**ribociclib 200 mg tablet, 63**

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**Caution** QT interval monitoring is required for patients treated with this drug.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**
Locally advanced or metastatic breast cancer
Treatment Phase: Initial treatment

**Clinical criteria:**
• Patient must not have previously been treated with an aromatase inhibitor for advanced or metastatic breast cancer, AND
• Patient must not have previously been treated with abemaciclib or palbociclib; OR
• Patient must have developed an intolerance to abemaciclib or palbociclib of a severity necessitating permanent treatment withdrawal, AND
• The condition must be hormone receptor positive, AND
• The condition must be human epidermal growth factor receptor 2 (HER2) negative, AND
• The condition must be inoperable, AND
• Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, AND
• The treatment must be in combination with anastrozole or letrozole, AND
• The treatment must not be in combination with abemaciclib or palbociclib, AND
• Patient must require dosage reduction requiring a pack of 42 tablets.

**Population criteria:**
• Patient must not be premenopausal.

**Authority required**
Locally advanced or metastatic breast cancer
Treatment Phase: Continuing treatment

**Clinical criteria:**
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
• Patient must not develop disease progression while receiving treatment with this drug for this condition, AND
• Patient must have stable or responding disease, AND
• The treatment must be in combination with anastrozole or letrozole, AND
• The treatment must not be in combination with abemaciclib or palbociclib, AND
• Patient must require dosage reduction requiring a pack of 42 tablets.

**Population criteria:**
• Patient must not be premenopausal.
A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

### RUXOLITINIB

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note** No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

**Note** Special Pricing Arrangements apply.

**Authority required**

High risk and intermediate-2 risk myelofibrosis

**Clinical criteria:**

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

**Authority required**

Intermediate-1 risk myelofibrosis

**Clinical criteria:**

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

### RUXOLITINIB

**Note** Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

**Note** Written applications for authority to prescribe should be forwarded to:
Department of Human Services Complex Programs
Reply Paid 9826
HOBART TAS 7001

**Note** No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

**Note** Special Pricing Arrangements apply.

**Authority required**

High risk and intermediate-2 risk myelofibrosis

**Clinical criteria:**

- The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis.

**Note** The authority application must be made in writing and must include:

1. A completed authority prescription form; and
2. A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:
   a. A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and
   b. A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

**Authority required**

Intermediate-1 risk myelofibrosis
### Ruxolitinib 5 mg tablet, 56

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### Sorafenib

#### 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.

**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:**
- The patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) following prior treatment with a tyrosine kinase inhibitor, **AND**
- The 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.

### Sorafenib 200 mg tablet, 60

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### Sorafenib

**Note**
- **Response Evaluation Criteria In Solid Tumours (RECIST)** is defined as follows:
  - **Complete response (CR)** is disappearance of all target lesions.
  - **Partial response (PR)** is a 30% decrease in the sum of the longest diameter of target lesions.
  - **Progressive disease (PD)** is a 20% increase in the sum of the longest diameter of target lesions.
  - **Stable disease (SD)** is small changes that do not meet above criteria.

**Note**
- No increase in the maximum quantity or number of units may be authorised.
- No increase in the maximum number of repeats may be authorised.
- Special Pricing Arrangements apply.

#### Authority required
- **STREAMLINED** 7487
  - Stage IV clear cell variant renal cell carcinoma (RCC) Treatment Phase: Continuing treatment beyond 3 months
  - **Clinical criteria:**
• Patient must have received an initial 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.

**Sorafenib 200 mg tablet, 60**

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**Sorafenib**

**Note** Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization.

**Sorafenib**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**10960**

Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Initial treatment

**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, **AND**
- The condition must be untreated with systemic therapy; OR
- Patient must have developed intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal.

**Authority required (STREAMLINED)**

**8617**

Advanced Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition.

**Sunitinib 200 mg tablet, 60**

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**Sunitinib**

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

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

**Note** Special Pricing Arrangements apply.

**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.

**Sunitinib 12.5 mg capsule, 28**

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**SUNITINIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

7471
Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

**Clinical criteria:**
- Patient must have received an initial authority prescription for this drug for this condition, **AND**
- Patient must not have disease progression, **AND**
- The treatment must be as monotherapy.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

sunitinib 12.5 mg capsule, 28

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sunitinib 25 mg capsule, 28

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sunitinib 37.5 mg capsule, 28

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**SUNITINIB**

**Note** Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
- Stable disease (SD) is small changes that do not meet above criteria.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

7466
Stage IV clear cell variant renal cell carcinoma (RCC)

**Clinical criteria:**
- Patient must have received an initial 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 tyrosine kinase inhibitor 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.

Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.

sunitinib 12.5 mg capsule, 28

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**SUNITINIB**

- Note: Sunitinib malate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.
- Note: Written applications for authority to prescribe should be forwarded to:
  - Department of Human Services
  - Complex Drugs
  - Reply Paid 9826
  - HOBART TAS 7001
- Note: No increase in the maximum quantity or number of units may be authorised.
- Note: No increase in the maximum number of repeats may be authorised.
- Note: Special Pricing Arrangements apply.

**Authority required**

Metastatic or unresectable malignant gastrointestinal stromal tumour
Treatment Phase: Initial treatment
Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have previously failed or be intolerant to imatinib mesilate.

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; 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.

sunitinib 12.5 mg capsule, 28
9488J

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**SUNITINIB**

- Note: No increase in the maximum quantity or number of units may be authorised.
- Note: No increase in the maximum number of repeats may be authorised.
- Note: Special Pricing Arrangements apply.
- Note: Patients who have developed intolerance to pazopanib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.
- Note: Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

**Authority required (STREAMLINED)**

9210
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Initial treatment
Clinical criteria:

- The condition must be classified as favourable to intermediate risk according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), **AND**
• Patient must have a WHO performance status of 2 or less, **AND**
• The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.
Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.

### SUNITINIB

**Note** A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note** Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS subsidised imatinib after progression on this drug.

**Note** Sunitinib malate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.

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

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

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

**7430**
Metastatic or unresectable malignant gastrointestinal stromal tumour
Treatment Phase: Continuing treatment

**Clinical criteria:**
• Patient must have received an initial authority prescription for this drug for this condition, **AND**
• The treatment must be as monotherapy, **AND**
• Patient must have a WHO performance status of 2 or less, **AND**
• Patient must not have progressive disease.

### sunitinib 12.5 mg capsule, 28

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### TRAMETINIB

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

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

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

**10051**
Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Initial treatment

**Clinical criteria:**
• Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition.
TRAMETINIB

Note A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

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

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

Note Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**6752**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

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TRAMETINIB

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

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

Note Special Pricing Arrangements apply.

**Authority required**

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:
- The treatment must be adjuvant to complete surgical resection, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition, **AND**
- Patient must have stable or responding disease.

**Authority required**

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously been issued with an authority prescription for trametinib and dabrafenib concomitantly for adjuvant treatment following complete surgical resection, **AND**
- Patient must not have experienced disease recurrence, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

**Authority required**

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Grandfather treatment

Clinical criteria:
- Patient must have previously received non-PBS subsidised drug for adjuvant treatment following complete surgical resection prior to 1 November 2019, **AND**
- The condition must be positive for a BRAF V600 mutation, **AND**
- Patient must have a WHO performance status of 1 or less prior to starting non-PBS treatment with this drug, **AND**
- Patient must not have evidence of recurrence, **AND**
- Patient must be receiving PBS-subsidised trametinib and dabrafenib concomitantly for this condition, **AND**
- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
• Patient must have commenced non-PBS-subsidised treatment within 12 weeks of complete surgical resection, \textbf{AND}
• Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

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\textbf{VEMURAFENIB}

\textbf{Note} No increase in the maximum quantity or number of units may be authorised.
\textbf{Note} No increase in the maximum number of repeats may be authorised.
\textbf{Note} Special Pricing Arrangements apply.

\textbf{VEMURAFENIB}

\begin{itemize}
\item A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.
\end{itemize}

\textbf{Authority required (STREAMLINED)}

\begin{itemize}
\item 10157
\item Unresectable Stage III or Stage IV malignant melanoma
\item Treatment Phase: Initial treatment
\item \textbf{Clinical criteria:}
\item The condition must be positive for a BRAF V600 mutation, \textbf{AND}
\item The condition must not have been treated previously with PBS-subsidised BRAF inhibitor therapy for unresectable Stage III or Stage IV disease; OR
\item Patient must have developed intolerance to other BRAF inhibitors of a severity necessitating permanent treatment withdrawal, \textbf{AND}
\item Patient must not have experienced disease progression whilst on adjuvant BRAF inhibitor treatment or disease recurrence within 6 months of completion of adjuvant BRAF inhibitor with MEK inhibitor treatment if previously treated for resected Stage IIIIB, IIIC or IIID melanoma, \textbf{AND}
\item Patient must have a WHO performance status of 2 or less.
\end{itemize}

\begin{tabular}{|l|c|c|c|c|c|} \hline \textbf{vemurafenib 240 mg tablet, 56} & \textbf{Max Qty Packs} & \textbf{No. of Rpts} & \textbf{Premium $} & \textbf{DPMQ $} & \textbf{MRVSN $} \tabularnewline \hline 11076Y & 4 & 3 & .. & *7049.50 & 41.00 \tabularnewline \hline \end{tabular}

\textbf{VEMURAFENIB}

\begin{itemize}
\item A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.
\item A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.
\item No increase in the maximum quantity or number of units may be authorised.
\item No increase in the maximum number of repeats may be authorised.
\end{itemize}

\textbf{Authority required (STREAMLINED)}

\begin{itemize}
\item 6013
\item Unresectable Stage III or Stage IV malignant melanoma
\item Treatment Phase: Continuing treatment
\item \textbf{Clinical criteria:}
\item Patient must have previously been issued with an authority prescription for this drug, \textbf{AND}
\item Patient must have stable or responding disease.
\end{itemize}

\begin{tabular}{|l|c|c|c|c|c|} \hline \textbf{vemurafenib 240 mg tablet, 56} & \textbf{Max Qty Packs} & \textbf{No. of Rpts} & \textbf{Premium $} & \textbf{DPMQ $} & \textbf{MRVSN $} \tabularnewline \hline 11081F & 4 & 5 & .. & *7049.50 & 41.00 \tabularnewline \hline \end{tabular}

\textbf{HYDROXYCARBAMIDE (HYDROXYUREA)}

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\textbf{IDELALISIB}

\begin{itemize}
\item No increase in the maximum quantity or number of units may be authorised.
\item No increase in the maximum number of repeats may be authorised.
\end{itemize}

\textbf{Note} Special Pricing Arrangements apply.
**Authority required**  
Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)  
Treatment Phase: Initial treatment  

**Clinical criteria:**  
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**  
- The treatment must be in combination with rituximab for up to a maximum of 8 doses, followed by monotherapy, **AND**  
- The condition must have relapsed or be refractory to at least one prior therapy, **AND**  
- The condition must be CD20 positive, **AND**  
- Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage), **AND**  
- Patient must be inappropriate for chemo-immunotherapy.  

A patient can be considered inappropriate for chemo-immunotherapy when one or more of the following are experienced:  
1. Severe neutropenia defined as absolute neutrophil count of less than or equal to 1.0 x 10⁹/L; or  
2. Severe thrombocytopenia defined as platelet count of less than or equal to 50 x 10⁹/L; or  
3. Evidence of one or more 17p chromosomal deletions demonstrated by fluorescence in situ hybridisation (FISH).  

Full blood count results 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;  
b) A completed CLL/SLL PBS Authority Application - Supporting information form; and  
c) Pathology report indicating that the patient can be considered inappropriate for chemo-immunotherapy due to one or more of the following:  
1) Recent severe neutropenia; or  
2) Recent severe thrombocytopenia; or  
3) Presence of 17p chromosomal deletion using fluorescence in situ hybridisation (FISH).  

A Grandfathered patient who has previously received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2017 must have met all the initial restriction criteria prior to initiating non-PBS subsidised treatment. A Grandfathered patient 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** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001  

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**Authority required**  
Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)  
Treatment Phase: Continuing treatment  

**Clinical criteria:**  
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**  
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.  

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  

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**idelalisib 100 mg tablet, 60**  

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**idelalisib**  

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

---  

**Authority required**  
Refractory follicular B-cell non-Hodgkin's lymphoma  
Treatment Phase: Initial treatment  

**Clinical criteria:**  
- The condition must be refractory to a prior therapy with rituximab, **AND**  
- The condition must be refractory to a prior therapy with an alkylating agent, **AND**  
- The treatment must be the sole PBS subsidised treatment for this condition.
The condition is considered refractory to a prior therapy when the patient experiences less than a partial response or progression of disease within 6 months after completion of the prior therapy.

The condition is considered refractory to both rituximab and an alkylating agent if the agents were administered together or in successive treatment regimens.

The authority application must be made in writing and must include:

a) A completed authority prescription form; and

b) A completed Refractory follicular B-cell non-Hodgkin's lymphoma PBS Authority Application - Supporting information form which must include date of completion of prior therapies with rituximab and an alkylating agent.

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

Prescribing information (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 this drug should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

**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).

---

### Olaparib

**Caution** Do not substitute olaparib 50 mg capsules with olaparib 100 mg or 150 mg tablets on a mg to mg basis due to difference in dosing and bioavailability of each formulation.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

10937
High grade epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuing treatment - second line treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug as a second line therapy for this condition, **AND**
- The treatment must be the sole PBS subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GGCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

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#### Idelalisib

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#### Olaparib

**Caution** Do not substitute olaparib 50 mg capsules with olaparib 100 mg or 150 mg tablets on a mg to mg basis due to difference in dosing and bioavailability of each formulation.

**Note** Special Pricing Arrangements apply.

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**Notes:**

- **General**
- **Antineoplastic and Immunomodulating Agents**
- **Schedule of Pharmaceutical Benefits – December 2020**
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Special Pricing Arrangements apply.

**Authority required**
High grade epithelial ovarian, fallopian tube or primary peritoneal cancer
Treatment Phase: Initial treatment - second line treatment

**Clinical criteria:**
- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- The condition must be platinum sensitive, **AND**
- Patient must have received at least two previous platinum-containing regimens, **AND**
- Patient must have relapsed following a previous platinum-containing regimen, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Platinum sensitivity is defined as disease progression greater than 6 months after completion of the penultimate platinum regimen.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

---

**OLAPARIB**

**Caution** Do not substitute olaparib 50 mg capsules with olaparib 100 mg or 150 mg tablets on a mg to mg basis due to difference in dosing and bioavailability of each formulation.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Special Pricing Arrangements apply.

**Authority required**
High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer
Treatment Phase: Initial treatment - first line treatment

**Clinical criteria:**
- The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

---

**OLAPARIB**

**Caution** Do not substitute olaparib 50 mg capsules with olaparib 100 mg or 150 mg tablets on a mg to mg basis due to difference in dosing and bioavailability of each formulation.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note Special Pricing Arrangements apply.

**Authority required**
High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer
Treatment Phase: Continuing treatment - first line treatment

**Clinical criteria:**
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, AND
- The treatment must not exceed a total of 24 months of combined non-PBS-subsidised and PBS-subsidised treatment for patients who are in complete response.

**olaparib 100 mg tablet, 56**

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**SONIDEGIB**

Caution Sonidegib 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 20 months and 6 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic or locally advanced basal cell carcinoma

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- The condition must be inappropriate for surgery, AND
- The condition must be inappropriate for curative radiotherapy, AND
- Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; OR
- Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made in writing and must include:
- a) A completed authority prescription form; and
- b) A completed Basal Cell Carcinoma Initial PBS Authority Application Form - Supporting Information Form; and
- c) A histological confirmation of BCC and whether the condition is metastatic or locally advanced; and
- d) A letter from a surgically qualified clinician demonstrating inappropriateness for surgery for patients with locally advanced BCC; and
- e) A letter from a radiation oncologist demonstrating inappropriateness for curative radiotherapy for patients with locally advanced BCC; and
- f) A signed patient acknowledgement.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

**Inappropriate for surgery is defined as:**
- i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or
- ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or
- iii/ Medical contraindication to surgery

**Inappropriate for curative radiotherapy is defined as:**
- i/ Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or
- ii/ Limitations due to location of tumour; or
- iii/ Limitations due to cumulative prior radiotherapy dose; or
- iv/ Progressive disease despite prior irradiation of locally advanced BCC.

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

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

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

**Authority required**
Metastatic or locally advanced basal cell carcinoma
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must remain inappropriate for surgery, **AND**
- The condition must remain inappropriate for curative radiotherapy, **AND**
- Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

The authority application must be made in writing and must include:
- A completed authority prescription form; and
- A completed Basal Cell Carcinoma Continuing PBS Authority Application Form - Supporting Information Form; and
- A confirmation statement from the treating doctor that the disease has not progressed; and
- In patients with locally advanced BCC, a letter from a surgically qualified clinician demonstrating that the condition remains inappropriate for surgery; or a letter from a radiation oncologist demonstrating that the condition remains inappropriate for curative radiotherapy.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

**Inappropriate for surgery is defined as:**
- Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or
- Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or
- Medical contraindication to surgery

**Inappropriate for curative radiotherapy is defined as:**
- Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or
- Limitations due to location of tumour; or
- Limitations due to cumulative prior radiotherapy dose; or
- Progressive disease despite prior irradiation of locally advanced BCC

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

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

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

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**sonidegib 200 mg capsule, 30**

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**VENETOCLAX**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic lymphocytic leukaemia (CLL)
Treatment Phase: Initial treatment - Dose titration

**Clinical criteria:**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
• Patient must be considered unsuitable for treatment or retreatment with a purine analogue, **AND**
• The condition must have relapsed or be refractory to at least one prior therapy, **AND**
• Patient must have a WHO performance status of 0 or 1, **AND**
• The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
• The treatment must be used as monotherapy for this condition under this restriction.

A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following:

a) Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;
b) Age is 70 years or older;
c) Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylating agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen;
d) History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;
e) Evidence of one or more 17p chromosomal deletions demonstrated by fluorescence in situ hybridisation (FISH).

**VENETOCLAX**

**Note**

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

**Note**

Special Pricing Arrangements apply.

**Note**

Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

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### Authority required

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: Dose modification

**Clinical criteria:**

• The treatment must be for dose titration purposes.

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### VENETOCLAX

**Note**

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

**Note**

Special Pricing Arrangements apply.

**Note**

Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

---

### Authority required

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Continuing treatment

**Clinical criteria:**

• Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
• The treatment must be in combination with rituximab for up to a maximum of 6 cycles, followed by monotherapy, **AND**
• The treatment must be used as monotherapy for this condition under this restriction.

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### venetoclax 100 mg tablet, 120

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### VENETOCLAX

**Note**

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

**Note**

Special Pricing Arrangements apply.

**Note**

Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
**Authority required**
Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

**Clinical criteria:**
- The condition must be untreated, **AND**
- Patient must be inappropriate for fludarabine based chemo-immunotherapy, **AND**
- The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses), **AND**
- Patient must have a creatinine clearance 30 mL/min or greater, **AND**
- Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage); OR
- Patient must have a creatinine clearance less than 70 mL/min.

venetoclax 10 mg tablet [14] (&) venetoclax 50 mg tablet [7] (&) venetoclax 100 mg tablet [7] (&) venetoclax 100 mg tablet [14], 1 pack

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**VENETOCLAX**

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.
**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**
Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must cease upon disease progression; OR
- The treatment must cease upon completion of 12 cycles of treatment with this drug for this condition, whichever comes first.

venetoclax 100 mg tablet, 120

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**VENETOCLAX**

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.
**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**
Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses), **AND**
- The treatment must cease upon disease progression.

venetoclax 100 mg tablet, 120

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**VISMODEGIB**

**Caution** Vismodegib 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 24 months and 2 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

**Authority required**
Metastatic or locally advanced basal cell carcinoma

**Clinical criteria:**
• The condition must be inappropriate for surgery, AND
• The condition must be inappropriate for curative radiotherapy, AND
• Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; OR
• Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.
The authority application must be made in writing and must include:
  a) A completed authority prescription form; and
  b) A completed Basal Cell Carcinoma Initial PBS Authority Application Form - Supporting Information Form; and
  c) A histological confirmation of BCC and whether the condition is metastatic or locally advanced; and
  d) A letter from a surgically qualified clinician demonstrating inappropriateness for surgery for patients with locally advanced BCC; and
  e) A letter from a radiation oncologist demonstrating inappropriateness for curative radiotherapy for patients with locally advanced BCC; and
  f) A signed patient acknowledgement.
The assessment of the patient’s response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Inappropriate for surgery is defined as:
  i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or
  ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or
  iii/ Medical contraindication to surgery

Inappropriate for curative radiotherapy is defined as:
  i/ Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or
  ii/ Limitations due to location of tumour; or
  iii/ Limitations due to cumulative prior radiotherapy dose; or
  iv/ Progressive disease despite prior irradiation of locally advanced BCC.

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

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

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001
iii/ Medical contraindication to surgery

Inappropriate for curative radiotherapy is defined as:

i/ Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

ii/ Limitations due to location of tumour; or

iii/ Limitations due to cumulative prior radiotherapy dose; or

iv/ Progressive disease despite prior irradiation of locally advanced BCC

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic or locally advanced basal cell carcinoma

Treatment Phase: Initial treatment or Continuing treatment – balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, AND

- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

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).

vismodegib 150 mg capsule, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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\[VORINOSTAT\]

Note: Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

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

Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have received systemic treatment with chemotherapy, AND

- Patient must demonstrate relapsed or chemotherapy-refractory disease, AND

- Patient must be ineligible for stem cell transplant, AND

- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed cutaneous T-cell lymphoma (CTCL) initial PBS Authority Application - Supporting Information Form.

\[VORINOSTAT\]

Note: Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

\[Authority required\]
Cutaneous T-cell lymphoma
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

vorinostat 100 mg capsule, 120

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ENDOCRINE THERAPY
HORMONES AND RELATED AGENTS

Progestogens

MEDROXYPROGESTERONE

Restricted benefit
Advanced breast cancer

Clinical criteria:
- The condition must be hormone receptor positive.

medroxyprogesterone acetate 500 mg tablet, 30

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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medroxyprogesterone acetate 100 mg tablet, 100

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medroxyprogesterone acetate 200 mg tablet, 60

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medroxyprogesterone acetate 250 mg tablet, 60

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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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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</table>

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
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.

---

**Restricted benefit**

**Anticipated premature ovarian failure**

**Clinical criteria:**
- Patient must be receiving treatment with an alkylating agent for a malignancy or an autoimmune disorder that has a high risk of causing premature ovarian failure, AND
- Patient must not receive more than 6 months’ treatment for this condition in a lifetime.

**Population criteria:**
- Patient must be pre-menopausal.

---

**goserelin 3.6 mg implant, 1**

<table>
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**GOSERELIN (&) BICALUTAMIDE**

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

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

---

**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.

---

**leuprorelin acetate 22.5 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

<table>
<thead>
<tr>
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**leuprorelin acetate 30 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe**

<table>
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<tr>
<th>Max. Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
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**leuprorelin acetate 7.5 mg modified release injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber syringe**

<table>
<thead>
<tr>
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<th>Packs</th>
<th>No. of Rpts</th>
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**leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack**

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leuprorelin acetate 30 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack
8709J

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leuprorelin acetate 45 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack
8859G

<table>
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leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe], 1 pack
8707G

<table>
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<td>41.00</td>
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leuprorelin acetate 45 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe
11943N

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<td>41.00</td>
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LEUPRORELIN

**Restricted benefit**
Central precocious puberty
Treatment Phase: Continuing treatment

**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.

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for this condition.

leuprorelin acetate 30 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe
11944P

<table>
<thead>
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LEUPRORELIN

**Restricted benefit**
Central precocious puberty
Treatment Phase: Initial treatment

**Treatment criteria:**
- Must be treated by a paediatric endocrinologist; OR
- Must be treated by an endocrinologist specialising in paediatrics.

**Population criteria:**
- Patient must be aged 10 years or younger (girls) or 11 years or younger (boys), AND
- Patient must have had onset of signs or symptoms of central precocious puberty prior to the age of 8 years (girls) or 9 years (boys).

**Restricted benefit**
Central precocious puberty
Treatment Phase: Initial - grandfather

**Clinical criteria:**
- Patient must have received treatment with a gonadotropin releasing hormone analogue (GnRHa) for this condition prior to 1 May 2015.

leuprorelin acetate 30 mg modified release injection [1 chamber] (&) inert substance diluent [1.5 mL chamber], 1 dual chamber syringe
11960L

<table>
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LEUPRORELIN (&) BICALUTAMIDE

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

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

**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.
leuprorelin acetate 7.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack

<table>
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<tr>
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leuprorelin acetate 22.5 mg modified release injection [1 syringe] (&) inert substance diluent [1 syringe] (&) bicalutamide 50 mg tablet [28], 1 pack

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TRIPTORELIN

Restricted benefit
Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

triptorelin 11.25 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

<table>
<thead>
<tr>
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triptorelin 22.5 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

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<th>Premium $</th>
<th>DPMQ $</th>
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triptorelin 3.75 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

<table>
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HORMONE ANTAGONISTS AND RELATED AGENTS

Anti-estrogens

TAMOXIFEN

Note This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.

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

Restricted benefit
Breast cancer
Clinical criteria:
• The condition must be hormone receptor positive.

tamoxifen 10 mg tablet, 60

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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</table>

TAMOXIFEN

Note For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

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

Restricted benefit
Breast cancer
Clinical criteria:
• The condition must be hormone receptor positive.

tamoxifen 20 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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<td>*27.54</td>
<td>28.83</td>
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TAMOXIFEN

Note This pharmaceutical benefit is not PBS-subsidised for primary prevention of breast cancer.
Note For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

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

Restricted benefit
Breast cancer
Clinical criteria:
• The condition must be hormone receptor positive.

tamoxifen 20 mg tablet, 60

<table>
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<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<td>GenFx Tamoxifen [GX]</td>
</tr>
<tr>
<td>Tamosin [AS]</td>
<td>Tamoxifen Sandoz [SZ]</td>
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</table>

TAMOXIFEN

Note A moderate risk of developing breast cancer is if the lifetime breast cancer risk is 1.5 to 3 times the population average. A high risk of developing breast cancer is if the lifetime breast cancer risk is more than 3 times the population average.

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

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

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

Restricted benefit
Reduction of breast cancer risk
Clinical criteria:
• Patient must have a moderate or high risk of developing breast cancer, AND
• The treatment must not exceed a dose of 20 mg per day, AND
• The treatment must not exceed a lifetime maximum of 5 years for this condition.

tamoxifen 20 mg tablet, 30

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genox 20 [AF]</td>
<td>Nolvadex-D [AP]</td>
</tr>
</tbody>
</table>

TOREMIFENE

toremifene 60 mg tablet, 30

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

Anti-androgens

BICALUTAMIDE

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

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

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

Authority required (STREAMLINED)

5729
Metastatic (stage D) carcinoma of the prostate
Clinical criteria:
• The treatment must be in combination with GnRH (LH-RH) analogue therapy.

bicalutamide 50 mg tablet, 28

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>APO-Bicalutamide [TX]</td>
<td>Bicalox [ER]</td>
</tr>
<tr>
<td>Calutex [AS]</td>
<td>Cosamide 50 [AF]</td>
</tr>
<tr>
<td>Cosudex [AP]</td>
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</tr>
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CYPROTERONE

cyproterone acetate 100 mg tablet, 50

<table>
<thead>
<tr>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTERONE 100 [RW]</td>
<td>APO-Cyproterone [TX]</td>
</tr>
<tr>
<td>Cyprocur 100 [AS]</td>
<td>Cyproterone 100 [AF]</td>
</tr>
<tr>
<td>Cyprostat-100 [SY]</td>
<td>Cyproterone AN [EA]</td>
</tr>
</tbody>
</table>
**ENZALUTAMIDE**

*Note* Special Pricing Arrangements apply.

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

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

**Authoritative 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.

**ENZALUTAMIDE 40 mg capsule, 112**

<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>3552.60</td>
<td>41.00</td>
<td>Xtandi [LL]</td>
</tr>
</tbody>
</table>

**FLUTAMIDE**

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

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

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

**Authoritative required (STREAMLINED)**

**FLUTAMIDE 250 mg tablet, 100**

<table>
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<tbody>
<tr>
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<td>5</td>
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<td>174.26</td>
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<td>Flutamin [AF]</td>
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</table>

**NILUTAMIDE**

*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.

**Authoritative required (STREAMLINED)**

**NILUTAMIDE 500 mg capsule, 112**

<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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</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td></td>
<td>3552.60</td>
<td>41.00</td>
<td>Xtandi [LL]</td>
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</table>
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

<table>
<thead>
<tr>
<th>nilutamide 150 mg tablet, 30</th>
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<tbody>
<tr>
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</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
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</tr>
</tbody>
</table>

### Aromatase inhibitors

#### ANASTROZOLE

- **Note**: This drug is not PBS-subsidised for primary prevention of breast cancer.
- **Note**: 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.

**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.

**Restricted benefit**
Breast cancer

**Clinical criteria:**
- The condition must be hormone receptor positive.

<table>
<thead>
<tr>
<th>anastrozole 1 mg tablet, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>8179L</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
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<tr>
<td></td>
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<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

#### EXEMESTANE

**Restricted benefit**
Metastatic (Stage IV) breast cancer

**Clinical criteria:**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

**Population criteria:**
- Patient must not be pre-menopausal.

<table>
<thead>
<tr>
<th>exemestane 25 mg tablet, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>10103R</td>
</tr>
<tr>
<td>Max Qty Packs</td>
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<td>1</td>
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<td></td>
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</table>

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

<table>
<thead>
<tr>
<th>exemestane 25 mg tablet, 30</th>
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<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

**LETROZOLE**

- **Note**: This drug is not PBS-subsidised for primary prevention of breast cancer.
- **Note**: 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.

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

Restricted benefit
Breast cancer
Clinical criteria:
• The condition must be hormone receptor positive.

Letrozole 2.5 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>8245Y</td>
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<td>31.81</td>
<td>33.10</td>
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</table>

* APO-Letrozole [TX]
* Femara 2.5 mg [NV]
* Femalet [AF]
* Letrozole APOTEX [GX]
* Gynotril [ER]
* Letrozole GH [HQ]
* Letrozole FBM [FO]
* Letrozole Sandoz [SZ]
* Pharmacor Letrozole 2.5 [CR]

Other hormone antagonists and related agents

- ABIRATERONE
  Note Special Pricing Arrangements apply.

Authority required
Castration resistant metastatic carcinoma of the prostate
Clinical criteria:
• The treatment must be used in combination with a corticosteroid, 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.

Abiraterone acetate 250 mg tablet, 120

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
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<td>3457.82</td>
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</tbody>
</table>

Zytiga [JC]

Abiraterone acetate 500 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>
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<td>41.00</td>
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</table>

Zytiga [JC]

- DEGARELIX

Restricted benefit
Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

Degarelix 80 mg injection [1 vial] (&) inert substance diluent [1 syringe], 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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<td>401.82</td>
<td>41.00</td>
</tr>
</tbody>
</table>

Firmagon 80mg [FP]

Degarelix 120 mg injection [2 vials] (&) inert substance diluent [2 syringes], 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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</thead>
<tbody>
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<td>2785N</td>
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<td>420.28</td>
<td>41.00</td>
</tr>
</tbody>
</table>

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
Clinical criteria:
• Patient must have excessive thrombocytosis.
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

#### General

**interferon alfa-2a 9 million units (33.333 microgram)/0.5 mL injection, 0.5 mL syringe**

<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>4</td>
<td>..</td>
<td>*416.84</td>
<td>41.00</td>
<td>Roferon-A [RO]</td>
</tr>
</tbody>
</table>

**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**

**Clinical criteria:**
- The condition must have clinical features suggestive of a poor prognosis, **AND**
- The treatment must be in combination with anthracycline-based chemotherapy.

**interferon alfa-2a 3 million units (11.111 microgram)/0.5 mL injection, 0.5 mL syringe**

<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>15</td>
<td>5</td>
<td>..</td>
<td>*416.94</td>
<td>41.00</td>
<td>Roferon-A [RO]</td>
</tr>
</tbody>
</table>

**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**

**Myeloproliferative disease**

**Clinical criteria:**
- Patient must have excessive thrombocytosis.

**interferon alfa-2a 3 million units (11.111 microgram)/0.5 mL injection, 0.5 mL syringe**

<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>15</td>
<td>4</td>
<td>..</td>
<td>*416.94</td>
<td>41.00</td>
<td>Roferon-A [RO]</td>
</tr>
</tbody>
</table>

**INTERFERON BETA-1A**

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

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

**Authority required (STREAMLINED)**

**7695**

**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 multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **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)**

**6860**

**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 received PBS-subsidised treatment with this drug for this condition, **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.

**interferon beta-1a 6 million units (30 microgram)/0.5 mL injection, 4 x 0.5 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>
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<td>869.01</td>
<td>41.00</td>
<td>Avonex [BD]</td>
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</table>
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

**General Pharmaceutical Benefits**

<table>
<thead>
<tr>
<th>Agent</th>
<th>Dose</th>
<th>Delivery</th>
<th>Max Qty</th>
<th>Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>interferon beta-1a 12 million units (44 microgram)/0.5 mL injection, 12 x 0.5 mL pen devices</td>
<td>8968B</td>
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<td>869.01</td>
<td>41.00</td>
<td>Rebib 44 [SG]</td>
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<tr>
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<tr>
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<td>9332E</td>
<td>1 5</td>
<td>..</td>
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**INTERFERON BETA-1B**

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

**Authority required (STREAMLINED)**

7695

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 multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, 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)**

6860

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 received PBS-subsidised treatment with this drug for this condition, 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.

<table>
<thead>
<tr>
<th>Agent</th>
<th>Dose</th>
<th>Delivery</th>
<th>Max Qty</th>
<th>Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>interferon beta-1b 8 million units (250 microgram) injection [15 vials] (&amp;) inert substance diluent [15 x 1.2 mL syringes], 1 pack</td>
<td>8101J</td>
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<td>1010.97</td>
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<td>Betaferon [BN]</td>
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**PEGINTERFERON ALFA-2A**

<table>
<thead>
<tr>
<th>Agent</th>
<th>Dose</th>
<th>Delivery</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>peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes</td>
<td>11416W</td>
<td>1 5</td>
<td>..</td>
<td>600.98</td>
<td>41.00</td>
<td>Pegasys [RO]</td>
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<td>Pegasys [RO]</td>
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**PEGINTERFERON BETA-1A**

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

**Authority required (STREAMLINED)**

7695

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

General Pharmaceutical Benefits 343
• Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, 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.

peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL pen device] & peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL pen device], 1 pack

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

peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL pen devices

<table>
<thead>
<tr>
<th></th>
<th>Max Qty Packs</th>
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**PEGINTERFERON BETA-1A**

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

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

**Authority required (STREAMLINED)**

6860
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 received PBS-subsidised treatment with this drug for this condition, 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.

peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL pen devices

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**Other immunostimulants**

**GLATIRAMER ACETATE**

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

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

**Authority required (STREAMLINED)**

7695
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 multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, 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)**

6860
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 received PBS-subsidised treatment with this drug for this condition, 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.

**MYCOBACTERIUM BOVIS (BACILLUS CALMETTE AND GUERIN (BCG)) TICE STRAIN**

Restricted benefit
Primary and relapsing superficial urothelial carcinoma of the bladder
Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Tice strain 500 million CFU injection, 3 vials

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### ABATACEPT

**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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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 (tocilizhumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

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 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)

Initial applications for a new patient (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, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to Services Australia within sufficient time to allow processing.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine (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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply. Assessment of the patient’s response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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-biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:
A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:
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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.
Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the baseline measurements.

Schedule of Pharmaceutical Benefits – December 2020
• 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.
• 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(s); and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

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.
- Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Continuing Treatment - balance of supply.

**Treatment criteria:**
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
• Patient must have received insufficient therapy with this drug for this condition 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.

**Note**
- Authority approval for sufficient therapy to complete the balance of supply 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).

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### abatacept 125 mg/mL injection, 4 x 1 mL pen devices

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"**ABATACEPT**

**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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:
- A patient may continue to receive long-term treatment with a PBS subsidised biological medicine while they continue to show a response to therapy.
- A patient cannot trial and fail, or cease to respond to, the same PBS subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

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 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
(ii) a patient has received prior PBS subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months).

Initial applications for a new patient (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, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition. Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to Services Australia within sufficient time to allow processing.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within
these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:
A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:
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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to take any treatment-free period.

(3) Baseline measurements to determine response.
Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, 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.
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 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, kneec 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 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.

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.

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.

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 and no repeats. The second prescription must be written for the subcutaneous formulation, 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.

It is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

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
The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

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General

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

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

**Authority required**
Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months).

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, 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.
- 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).

An 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, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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.

**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 subcutaneous formulation, 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.

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.

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 biological medicine.

**Note**
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

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

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

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition **5 times, AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **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.
- Major joints are defined as (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).
- All measures of joint count and ESR and/or CRP 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.
- The authority application must be made in writing and must include:
  - (1) a completed authority prescription form(s); and
  - (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

**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 subcutaneous formulation, 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.

It is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
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Complex Drugs
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HOBART TAS 7001

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General Pharmaceutical Benefits

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

**BARICITINIB**

**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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) α anti-antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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-α antagonist. A patient receiving PBS-subsidised biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- A patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- A patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure. 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 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months).
Initial applications for a new patient (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, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Assessment of the patient’s response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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-biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months which would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment applications must be assessed according to the revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the
response must be determined on the total number of major joints. Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

**Note** Special Pricing Arrangements apply.

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**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 September 2018, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have failed 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 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 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 have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

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

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.

All applications for treatment with this drug for this condition under this restriction must include baseline joint count and ESR and/or CRP as determined at the completion of a 6 month intensive DMARD trial but prior to ceasing DMARD therapy, and
measure of response to the prior course of non-PBS-subsidised therapy with this drug. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

A Grandfathered patient 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.

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.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, 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.

Population criteria:

- Patient must be aged 18 years or older.
- 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(s); and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

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 Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
BARICITINIB

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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leuкоencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

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 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24
General

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Initial applications for a new patient (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, belimumab, certolizumab pegol, efalizumab, etanercept, golimumab, infliximab, tocilizumab, tafamidis and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to Services Australia within sufficient time to allow processing.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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-biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first application for a biological medicine. However, prescribers may provide baseline measurements any time that an initial treatment-free period is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the
reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

Note Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- **Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, 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 a maximum tolerable dose of methotrexate must be documented in the application, if applicable.**

Note The application must include details of the contraindications and/or intolerances including severity.

The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

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. If met 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

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).

An 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, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.
Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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.

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.

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 biological medicine.

Note: Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
• Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, AND
• Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND
• Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, AND
• The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
• The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, AND
• The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

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

Major joints are defined as (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).

All measures of joint count and ESR and/or CRP 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

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.
General Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note
Authority approval for sufficient therapy to complete the balance of supply 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).

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- CLADRIBINE

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

Note
Special Pricing Arrangements apply.

Authority required (STREAMLINED) 10170
Relapsing remitting multiple sclerosis
Treatment Phase: Initial treatment

Clinical criteria:
- The condition must be diagnosed by a neurologist, AND
- 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
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, AND
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, 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.
The prescriber should write authority prescriptions for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.

Authority required (STREAMLINED) 10171
Relapsing remitting multiple sclerosis
Treatment Phase: Continuing treatment

Treatment criteria:
- Must be treated by a neurologist.
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, AND
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, 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.

The prescriber should request authority approval for the appropriate combination of packs (1, 4 or 6 tablets) to provide sufficient drug for a treatment week based on the weight of the patient in accordance with the TGA approved Product Information. Separate authority prescriptions may be required where the dose for treatment week 5 is different to the dose for treatment week 1.

cladribine 10 mg tablet, 1
11603Q
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1 1 4010.00 41.00 Mavenclad [SG]

cladribine 10 mg tablet, 4
11604R
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11611D
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-EVEROLIMUS-
Caution Careful monitoring of patients is mandatory.

everolimus 250 microgram tablet, 60
8840G
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
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-everolimus 1 mg tablet, 60
9352F
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
2 3 1691.24 41.00 Certican [NV]

-FINGOLIMOD-
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)
10198
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 the sole PBS-subsidised disease modifying therapy for this condition, AND
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, AND
- Patient must be ambulatory (without assistance or support).

Population criteria:
- Patient must weigh 40 kg or less.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)
10093
Multiple sclerosis
Treatment Phase: Continuing treatment
Clinical criteria:
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, AND
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, 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.

Population criteria:
- Patient must weigh 40 kg or less.

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**FINGOLIMOD**

Note: No increase in the maximum quantity or number of units may be authorised.
Note: No increase in the maximum number of repeats may be authorised.
Note: Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

10162
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 the sole PBS-subsidised disease modifying therapy for this condition, AND
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, 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)**

10172
Multiple sclerosis
Treatment Phase: Continuing treatment

Clinical criteria:
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, AND
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, 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.

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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)**

5766
Severe active psoriatic arthritis

Clinical criteria:
- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, AND
- The treatment must be initiated by a physician.
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)

Severe active rheumatoid arthritis

Clinical criteria:
- Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR
- Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, AND
- The treatment must be initiated by a physician.

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

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.
### SIPONIMOD

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

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

**Note** Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Authority required (STREAMLINED)</th>
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<tbody>
<tr>
<td>Multiple sclerosis</td>
<td></td>
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<tr>
<td>Treatment Phase: Initial treatment</td>
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</tbody>
</table>

**Clinical criteria:**
- The condition must be/have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of at least one of the brain/spinal cord; OR
- The condition must be/have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis supported by written certification, which is documented in the patient's medical records, from 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 the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory, with/without assistance/support, **AND**
- Patient must have mild disability in at least 3 functional systems; OR
- Patient must have moderate disability in at least 1 functional system.

Functional systems referred to in this restriction are the: visual, brain stem, pyramidal, cerebellar, sensory, bowel/bladder and cerebral/cognitive systems.

Select a dose and pack size appropriate for the patient's CYP2C9 metabolising enzyme status.

**Note** There is no specific Medical Benefits Schedule item for CYP2C9 metabolising enzyme status testing.

<table>
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<tr>
<td>Multiple sclerosis</td>
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<tr>
<td>Treatment Phase: Continuing treatment (including recommencement of treatment)</td>
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</tbody>
</table>

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must be ambulatory, with/without assistance/support, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

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<tr>
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<tr>
<td>Multiple sclerosis</td>
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<tr>
<td>Treatment Phase: Grandfather treatment (transition from non-PBS-subsidised to PBS-subsidised treatment)</td>
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**Clinical criteria:**
- Patient must have commenced non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 November 2020, **AND**
- The condition must have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of at least one of the brain/spinal cord prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- The condition must have previously been diagnosed as clinically definite relapsing-remitting multiple sclerosis supported by written certification, which is documented in the patient's medical records, from a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have mild disability in at least 3 functional systems prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have moderate disability in at least 1 functional system prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must be ambulatory, with/without assistance/support, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Functional systems referred to in this restriction are the: visual, brain stem, pyramidal, cerebellar, sensory, bowel/bladder and cerebral/cognitive systems.

A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.
## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

### General Pharmaceutical Benefits

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<th>siropimod 250 microgram tablet, 120</th>
<th>siropimod 2 mg tablet, 28</th>
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<tr>
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<tr>
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<td>12158X</td>
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### SIROLIMUS

**Caution** Careful monitoring of patients is mandatory.

#### sirolimus 1 mg/mL oral liquid, 60 mL

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<td>sirolimus 1 mg tablet, 100</td>
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<td>sirolimus 2 mg tablet, 100</td>
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</table>

### 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.

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

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

#### Authority required (STREAMLINED)

1. **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 the sole PBS-subsidised disease modifying therapy for this condition, **AND**
     - Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **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.

2. **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 the sole PBS-subsidised disease modifying therapy for this condition, **AND**
     - Patient must have previously received PBS-subsidised treatment with this drug for this condition, **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 recorded in the patient's medical records.
**TOFACITINIB**

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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed or ceased to respond to treatment with 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

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 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has a break in treatment of longer than 24 months may commence a further course of treatment with a biological medicine under Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months).

Initial applications for a new patient (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, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to Services Australia within sufficient time to allow processing.

Abatacept patients:
A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Assessment of the patient’s response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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-biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

Note: Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase: Continuing treatment**

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **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.

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

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(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

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 Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

**Treatment criteria:**
• Must be treated by a rheumatologist; OR

• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
• Patient must have received insufficient therapy with this drug for this condition 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.

**Note**
Authority approval for sufficient therapy to complete the balance of supply 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).

**TOFACITINIB 5 mg tablet, 56**

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**TOFACITINIB**

**Note**
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may try biological medicines without having to experience a disease flare when swapping to the alternate biological medicine.
Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine therapy before they are eligible to commence another cycle [further details are under ‘(5) Recomencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recomencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recomencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Infliximab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine 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 with that biological medicine.

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.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

Note Special Pricing Arrangements apply.

Authority required
Severe psoriatic arthritis
Treatment Phase: Initial treatment - Grandfather treatment

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:
- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 May 2019, AND
- Patient must be receiving treatment with this drug for this condition at the time of application, 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 prior to initiating non-PBS subsidised treatment with this drug for this condition, 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 prior to initiating non-PBS subsidised treatment with this drug for this condition; 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 prior to initiating non-PBS subsidised treatment with this drug for this condition, AND
- Patient must have demonstrated an adequate response following at least 12 weeks of non-PBS-subsidised treatment with this drug for this condition, AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

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

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.

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 used to determine response for all subsequent continuing treatments.

The assessment of the patient’s response to this PBS-subsidised course of therapy must be conducted no later than 4
weeks from the cessation of the treatment course.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond
to treatment with this drug.

A patient 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.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) the date of commencement of this drug; and
- (4) results of the baseline patient assessment prior to initiation of non-PBS subsidised therapy with this drug.

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

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

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

**Authority required**
Severe psoriatic arthritis
Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this
  condition, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

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

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 used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.
Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient’s response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not sufficient within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment or Grandfathered patients - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Grandfathered 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.

**Note** Authority approval for sufficient therapy to complete the balance of supply 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).

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**Note** **TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

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 biological medicines and who has a break in treatment of less than 24 months may...
commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

1. How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months).

Initial applications for a new patient (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, baricitinib, etanercept, golimumab, tocilizumab, tocitakinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab. Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be re-submitted to Services Australia within 4 weeks to ensure continuation of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to Services Australia within sufficient time to allow processing. Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (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 biological medicine 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 at 12 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply. Assessment of the patient’s response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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-biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

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, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response. Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

Note: Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

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 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.
The authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.
It is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.
Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
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 The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, AND
• Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND
• Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

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

An 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, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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.

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.

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 biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.
- Major joints are defined as (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).

All measures of joint count and ESR and/or CRP 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.
The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
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Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, AND
• The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply 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).

tofacitinib 5 mg tablet, 56

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TOFACITINIB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when switching to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a
treatment failure. Once a patient has 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 medicine therapy before they are eligible to commence another cycle (further details are under (5) ‘Recommencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime. How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised biological medicine therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised biological medicine therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted 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. Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient. Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the
Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle. Within a treatment cycle a patient may alternate between any biological medicine of their choice (1 at a time) providing:
- they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.
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.

(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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment. 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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

**Note**
Special Pricing Arrangements apply.

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<td>Severe psoriatic arthritis</td>
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<td>Treatment Phase: Initial treatment - Initial 1 (new patient)</td>
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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 psoriatic arthritis.

**Clinical criteria:**
- Patient must not have received PBS-subsidised treatment with a biological medicine 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 aged 18 years or older.
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(s); and
(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.
An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

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)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis
Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less than 5 years)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during 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.
- 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 authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.
An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.
Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.
An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.
Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

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Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

• Must be treated by a rheumatologist; OR

• Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

• Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND

• Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND

• The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR

• The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, AND

• The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, AND

• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

• Patient must be aged 18 years or older.

Major joints are defined as (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).

All measures of joint count and ESR and/or CRP 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition 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 biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient’s response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

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

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UPADACITINIB

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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

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 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months),
(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)
months)
Initial applications for a new patient (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, baricitinib, etanercept, golimumab, tocilizumab, upadacitinib and infliximab pegol (depending upon the dosing regimen). 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to Services Australia within sufficient time to allow processing.

Abatacept patients:
A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient must 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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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-biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:
A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:
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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide baseline measurements any time that an initial treatment application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the
reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

Note Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **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.

**Population criteria:**

- Patient must be aged 18 years or older.

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 must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

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 Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Grandfathered patients

**Treatment criteria:**
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 May 2020, AND
• Patient must be receiving treatment with this drug for this condition at the time of application, AND
• Patient must have failed to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) prior to initiating non-PBS-subsidised treatment with this drug for this condition. This must have included at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must have been methotrexate at a dose of at least 20 mg weekly and one of which must have been: (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 to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs prior to initiating non-PBS-subsidised treatment with this drug for this condition. If methotrexate was contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or could not be tolerated at a 20 mg weekly dose, this intensive treatment must have included 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 to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs prior to initiating non-PBS-subsidised treatment with this drug for this condition. If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine were contraindicated according to the relevant TGA-approved Product Information or could not be tolerated at the doses specified above, the intensive treatment must have included at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs used in place of the DMARDs which were 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 have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, AND
• Patient must not receive more than 24 weeks of treatment under this restriction.

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

Patients must provide 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 following criteria indicate failure to have achieved an adequate response to DMARD treatment prior to initiating non-PBS-subsidised treatment with this drug for this condition:

Even if the baseline number of active joints is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

All applications for treatment with this drug for this condition under this restriction must include baseline joint count and ESR and/or CRP as determined at the completion of a 6 month intensive DMARD trial but prior to ceasing DMARD therapy. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

A Grandfathered patient 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 Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to:
Services Australia
Complex Drugs

General Pharmaceutical Benefits 387
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Continuing and Initial Grandfathered patients treatment - balance of supply

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; OR
- Patient must have received insufficient treatment with this drug to complete 24 weeks of treatment under the Initial treatment - Grandfathered patients, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

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

**Note**
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

upadacitinib 15 mg modified release tablet, 28

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**UPADACITINIB**

**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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:
  - a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
  - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.
- A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.
- 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 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction.

A length of treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

1. How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019:
   - (a) Initial treatment
     - Applications for initial treatment should be made where:
       - (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
       - (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or
       - (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).
     - (iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)
   - Initial applications for a new patient (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, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab.
General Pharmaceutical Benefits

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the count is based on total active joints (i.e. used for all subsequent courses of treatment). To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent courses of treatment and that where required an application is submitted to Services Australia within sufficient time to allow processing.

Abatacept patients:
A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply. Assessment of the patient’s response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(3) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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-biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months which would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:
A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:
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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period. Following abatacept or rituximab treatment, a patient may trial a course of an alternate biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:
A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:
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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period. Following abatacept or rituximab treatment, a patient may trial a course of an alternate biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:
A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:
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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period. Following abatacept or rituximab treatment, a patient may trial a course of an alternate biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:
A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:
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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine during the required treatment-free period. Following abatacept or rituximab treatment, a patient may trial a course of an alternate biological medicine if they have failed to respond to prior treatment with that drug.
Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

**Note** Special Pricing Arrangements apply.

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<td>Severe active rheumatoid arthritis</td>
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<td>Treatment Phase: Initial treatment - Initial 1 (new patient)</td>
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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.

**Clinical criteria:**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, 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.
- 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 following criteria indicate failure to achieve an adequate response to DMARD treatment 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 and/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 requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.
- Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.
- The authority application must be made in writing and must include:
  - (1) a completed authority prescription form(s); and
  - (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.
- To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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-subsیدised treatment with this drug for this condition.

**Note**

Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

---

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsیدised treatment with a biological medicine for this condition, AND
- Patient must not have failed to respond to previous PBS-subsیدised treatment with this drug for this condition, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsیدised biological medicine treatment for this condition 5 times, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

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).

An application for a patient who has received PBS-subsیدised 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-subsیدised treatment with this drug, conducted within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

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-subsیدised 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 biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, AND
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, AND
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, AND
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.
- Major joints are defined as (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).
- All measures of joint count, ESR and/or CRP must be no more than 4 weeks old at the time of application.
- If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.
- Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.
- The authority application must be made in writing and must include:
  1. a completed authority prescription form(s); and
  2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.
- To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.
- Where a response assessment is not conducted within the timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
- 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 Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
**General Pharmaceutical Benefits**

### Antineoplastic and Immunomodulating Agents

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<td>Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply</td>
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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.

#### Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note**: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hiPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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### Adalimumab

**Note**: Treatment of Paediatric Patients with Refractory Crohn Disease

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

### Authority required

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

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 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy 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 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 biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

For first and subsequent continuing courses of PBS-subsidised biological medicine therapy, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent Continuing treatment restrictions with that drug 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 supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 1 month of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction. A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(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 PCDAI submitted with the first authority application for a biological medicine. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

(4) Recom mencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retriav of conventional therapies is not required.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

Clinical criteria:

• Patient must have a documented history of severe Crohn disease, AND
• Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
• Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, AND
• Patient must have a total PCDAI score of 40 points or less, AND
• Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:
### Adalimumab 20 mg/0.4 mL Injection, 2 x 0.4 mL Syringes

- **Max Qty Packs**: 1
- **No. of Rpts**: 5
- **Premium $**: 1109.00
- **DPMQ $**: 41.00

### Adalimumab 40 mg/0.8 mL Injection, 2 x 0.8 mL Pen Devices

- **Max Qty Packs**: 1
- **No. of Rpts**: 5
- **Premium $**: 1109.00
- **DPMQ $**: 41.00

### Adalimumab 40 mg/0.8 mL Injection, 2 x 0.8 mL Syringes

- **Max Qty Packs**: 1
- **No. of Rpts**: 5
- **Premium $**: 1109.00
- **DPMQ $**: 41.00

### Adalimumab

**Note**: TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term “biological medicines” appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed, or ceased to respond to treatment for this condition 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 medicine therapy for this condition 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 medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy 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 3 trials or fewer of biological medicine therapy 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 biological medicine therapy after 1 August 2015.

(a) Initial treatment.
Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

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 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy 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 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 biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

For first and subsequent continuing courses of PBS-subsidised biological medicine therapy, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent Continuing treatment restrictions with that drug 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 supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 1 month of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).

A patient cannot swap to a biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(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 PCDAI submitted with the first authority application for a biological medicine. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

(4) Recomencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note: Authority approval for sufficient therapy to complete the balance of supply 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).

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**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 pen devices**

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**ADALIMUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alpha-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1 kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 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 medicine therapy for this condition 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 medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy 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 biological medicine therapy 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 adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September 2017.

(a) Initial treatment

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

From 1 September 2017, 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 or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, 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 biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

For subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, 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 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 supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine 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, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

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, within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(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 CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-trial of systemic therapy is not required.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe Crohn disease
Treatment Phase: Continuing treatment

Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition. AND
• Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
• Patient must have an adequate response to this drug defined as (a) an 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; or (ii) faeces: normalisation of lactoferrin or calprotectin level; 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), if affected by short gut syndrome, extensive small intestine or an ostomy patient, AND
• Patient must not receive more than 24 weeks of treatment under this restriction.

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

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 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, if relevant; or
(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

An application 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 conducted 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.

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 the Department of Human Services 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 the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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 quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.

| adalimumab | 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices |
| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ |
| 9191R | 1 | 5 | ... | 1109.00 | 41.00 |
| Humira [VE] |

| adalimumab | 40 mg/0.8 mL injection, 2 x 0.8 mL syringes |
| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ |
| 9189P | 1 | 5 | ... | 1109.00 | 41.00 |
| Humira [VE] |

### ADALIMUMAB

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

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

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Moderate to severe hidradenitis suppurativa

**Treatment Phase:** Initial treatment 1 - New patient or Initial treatment 2 - Recomencement of treatment – balance of supply

**Clinical criteria:**

• Patient must have received insufficient therapy with this drug for this condition under the Initial treatment 1 - New patient restriction to complete a maximum of 16 weeks treatment; OR

• Patient must have received insufficient therapy with this drug for this condition under the Initial treatment 2 - Recomencement of treatment restriction to complete a maximum of 16 weeks treatment.

**Treatment criteria:**

• Must be treated by a dermatologist.

A maximum of 12 weeks of treatment will be authorised under this restriction.
**adalimumab 40 mg/0.8 mL injection, 4 x 0.8 mL pen devices**

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**ADALIMUMAB**

**Note** No increase in the maximum quantity or number of units may be authorised.  
**Note** No increase in the maximum number of repeats may be authorised.  
**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001

**Authority required**

Moderate to severe hidradenitis suppurativa

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a dermatologist.
- A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.
- For the first application for continuing treatment a Hidradenitis Suppurativa Clinical Response (HiSCR) assessment must be made following a minimum of 12 weeks of treatment. For subsequent continuing treatment a HiSCR assessment must be made every 24 weeks.
- 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 must be provided 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 within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.
- A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.
- The authority application must be made in writing and must include:
  - (a) a completed authority prescription form; and
  - (b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

**TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term “biological medicines” appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time. For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed, or ceased to respond to treatment for this condition 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 medicine therapy for this condition 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 medicine treatment in the most recent cycle to the date of the first...
application for initial treatment with a biological medicine under the new treatment cycle. A patient who has failed fewer than 3 trials of biological medicine therapy 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 3 trials or fewer of biological medicine therapy 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 biological medicine therapy after 1 August 2015.

(a) Initial treatment. Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years). 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 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy 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 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 drug unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For first and subsequent continuing courses of PBS-subsidised biological medicine therapy, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent Continuing treatment restrictions with that drug 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 supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 1 month of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle. Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more). A patient cannot swap to a biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction. A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(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 PCDAI submitted with the first authority application for a biological medicine. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

(4) Recomencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retreatment of conventional therapies is not required.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, AND
- Patient must have 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; or (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; OR
- Patient must have documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, AND
- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) two completed authority prescription forms; and
(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.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.

If treatment with any of the specified prior conventional 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 Human Services website (www.humanservices.gov.au).

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) will be authorised.

Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater: one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg: one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug 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) and authorised through the Balance of Supply treatment phase PBS restriction. 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 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 the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.
Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Authority required**

Severe Crohn disease

**Treatment Phase:** Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**
- Patient must have a documented history of severe Crohn disease, AND
- Patient must have received prior PBS-subsidised treatment with this drug for this condition; OR
- Patient must have been assessed by a specialist paediatric gastroenterologist, with histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist.

Population criteria:
- Patient must have a current PCDAI score of 40 or greater, AND
- Patient must in this treatment cycle, have received prior PBS-subsidised treatment with infliximab and adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be no more than 1 month old at the time of application.

A PCDAI assessment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician (internal medicine specialising in gastroenterology (code 81)); OR
- Must be treated by a consultant physician (general medicine specialising in gastroenterology (code 82)); OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include:
- (a) two completed authority prescription forms; and
- (b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:
  (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and
  (ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug 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) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine 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 the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A PCDAI 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 the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Authority required**

Severe Crohn disease

**Treatment Phase:** Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, AND
### General

- Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 6 to 17 years inclusive.

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [intelligent medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation must be made in writing and must include:
- (a) two completed authority prescription forms; and
- (b) a completed paediatric Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.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.

The PCDAI 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 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) will be authorised.

Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater: one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg: one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug 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) and authorised through the Balance of Supply treatment phase PBS restriction. 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 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 the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

### Adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

<table>
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### Adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

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### Adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL pen devices

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### Adalimumab

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

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

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

404 Schedule of Pharmaceutical Benefits – December 2020
Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:
- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, AND
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be limited to a maximum duration of 16 weeks.

Treatment criteria:
- Must be treated by a dermatologist.
- Assessment of disease severity must be no more than 1 month old at the time of application.
- An assessment of the patient’s response to this recommencement course of treatment must be made following a minimum of 12 weeks of treatment.
- At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial treatment 1 - New patient or Initial treatment 2 - Recommenacement of treatment - balance of supply

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include:
(i) the Hurley stage grading; and
(ii) the AN count; and
(iii) the name of the antibiotic/s received for two separate courses each of three months; or
(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment 2 - Recommenacement of treatment

Clinical criteria:
- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, AND
- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be limited to a maximum duration of 16 weeks.

Treatment criteria:
- Must be treated by a dermatologist.
- Assessment of disease severity must be no more than 1 month old at the time of application.
- A response to treatment is defined as:
  Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.
- An assessment of the patient’s response to this recommencement course of treatment must be made following a minimum of 12 weeks of treatment.
- At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial treatment 1 - New patient or Initial treatment 2 - Recommenacement of treatment - balance of supply

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed hidradenitis suppurativa PBS authority application supporting Information form which must include:
(i) the Hurley stage grading; and
(ii) the AN count.

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL pen devices

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ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' 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 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine 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 biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to 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 biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine 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 biological medicine 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 under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine 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 under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

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 conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

For second and subsequent cycles of PBS-subsidised biological medicine, 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.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 biological medicine supply.

A patient is eligible for PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the patient must meet the biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine of more than 24 months.
medicine 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 timesframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine 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 biological medicine. 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) Recomencement of treatment after a 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, 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.

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

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.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note

All queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional
Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9626
HOBART TAS 7001

**Authority required**
Severe active juvenile idiopathic arthritis

**TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

**Treatment Phase: Continuing Treatment - balance of supply**

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug for this condition 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.

**Note** Authority approval for sufficient therapy to complete the balance of supply 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).

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### ADALIMUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab,
certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab for adult patients with ankylosing spondylitis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol,
etanercept, golimumab, infliximab, ixekizumab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 7 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a
biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab,
ixekizumab and secukinumab treatment prior to 1 December 2020 is considered to start their first cycle as of 1 December 2020.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological
medicine more than once.

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 medicine therapy before they are
eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-
subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with
a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines 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 biological medicines 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 biological medicine treatment with adalimumab, certolizumab pegol, etanercept,
golimumab, infliximab, ixekizumab and secukinumab:

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to
commence such therapy (Initial 1 - New patient)

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an
alternate agent (Initial 2 - Change or Recomencement of treatment after a break in therapy of less than 5 years) [further
details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised
therapy of less than 5 years with the same agent (Initial 2 - Change or Recomencement of treatment after a break in
therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of
more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks
of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine, it is recommended that a patient is
reviewed for response following a minimum of 12 weeks of therapy under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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 biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

Services Australia 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 biological medicine. 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 must be used 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 used to determine response.

Prescribers may provide new baseline measurements any time an ‘Initial treatment’ authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Authority required

Ankylosing spondylitis
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 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 ankylosing spondylitis.

The authority application must be made in writing and must include:
- a completed authority prescription form; and
- a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
- an ESR measurement no greater than 25 mm per hour; or
- a CRP measurement no greater than 10 mg per L; or
- an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.
Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au.

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

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 ankylosing spondylitis.

**Note** Authority approval for sufficient therapy to complete the balance of supply 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).

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**ADALIMUMAB**

**Note** **TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab or vedolizumab at any one time.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, golimumab, infliximab and vedolizumab only.

From 1 June 2018, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2018 is considered to start their first cycle as of 1 June 2018. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. 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 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 medicine treatment in the most recent cycle to the date of the first application for initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine 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 under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle under the Initial 3 treatment restrictions.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment after 1 June 2018.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) an adult patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) an adult patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping therapy' below];
(iii) an adult patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years); or
(iv) an adult patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab. For the second and subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(2) Continuing treatment.

For the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 biological medicine supply.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine treatment is approved, a patient may swap to an alternate biological medicine treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

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.

(4) Recommmencement 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 biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the scores of disease severity.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following NOTES and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time. From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive their long-term treatment with a biological medicine while they are assessed to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicine 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 medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine 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 under the Initial 2 treatment restriction. A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under ‘Swapping treatment’ below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised...
therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab. For the second and subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

Adalimumab only:

Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the continuing treatment restriction 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 PBS subsidy criteria are met.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine 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 these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

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

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with 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.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of 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 sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.
A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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).

### Authority required

- Moderate to severe ulcerative colitis
- Treatment Phase: Continuing treatment - balance of supply

### Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

### Clinical criteria:

- Patient must have received insufficient therapy with this drug 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 this restriction.

Note Authority approval for sufficient therapy to complete the balance of supply 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).

### ADALIMUMAB

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### ADALIMUMAB

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' 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 PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment 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 adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 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 medicine therapy for this condition 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 adalimumab or infliximab treatment in the most recent treatment cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy 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 3 trials or fewer of biological medicine therapy 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 adalimumab or infliximab therapy after 1 April 2011.
2. Initial treatment.
3. Applications for initial treatment should be made where:
   1. a patient has received no prior PBS-subsidised adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial treatment: new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1); or
   2. a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under 'Swapping therapy' below]; or
   3. a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Change or Recommencement of treatment after a break in therapy of less than 5 years (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 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 biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For subsequent courses of PBS-subsidised adalimumab or infliximab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services 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. Adalimumab patients:

Following the completion of an initial treatment course with adalimumab, 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 treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Infliximab patients:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions. For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle. A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction. A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(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 submitted with the first authority application for adalimumab or infliximab. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

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

Note: No increase in the maximum number of repeats may be authorised.
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 which includes a completed Fistula Assessment form including the date of the assessment of the patient’s condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy following a minimum of 12 weeks of therapy.

It is recommended that an application for continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment to ensure continuity of treatment for those patients who meet the continuation criteria for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

A maximum of 24 weeks treatment will be authorised under this restriction.

Note

Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**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.

Note

Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

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### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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**ADALIMUMAB**

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS subsidised biological medicine.
treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine therapy before they are eligible to commence another cycle [further details are under ‘(5) Recommencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below];

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years);

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted 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.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tocafcitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity. A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle. Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine 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 with that biological medicine.

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.

(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 medicine. However, prescribers may provide new baseline measurements any time that an initial change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment. 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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

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

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 used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and
(2) a completed Severe Psoriatic Arthritis PBS Authority Application – Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient’s response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition 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 the balance of supply 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).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

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ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term ‘biological medicine’ appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alpha-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 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 medicine therapy for this condition 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 medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy 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 biological medicine therapy 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 adalimumab, infliximab, vedolizumab or ustekinumab therapy after 1 September

418 Schedule of Pharmaceutical Benefits – December 2020
Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy Initial 1 (new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine and wishes to trial an alternate agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (change or recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years).

From 1 September 2017, 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 or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, 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 biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

For subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

Ustekinumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 2 vials of 45 mg and no repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, 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 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 supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient may swap if eligible to the alternate biological medicine 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, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

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, within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(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 CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

(4) Recommmencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retreatment of systemic therapy is not required.

**Authority required**

Severe Crohn disease

**Treatment Phase: Initial treatment - Initial 1 (new patient)**

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician (internal medicine specialising in gastroenterology (code 81)); OR
• Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

• Patient must be aged 18 years or older.

**Clinical criteria:**

• Patient must have confirmed severe 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, **AND**
• Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
• Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; **OR**
• Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; **OR**
• Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
• Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
• Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; **OR**
• Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; **OR**
• Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

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 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 if relevant; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and
(iv) the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;
(b) patient must be assessed clinically as being in a high faecal output state;
(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(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; or
(ii) faeces: higher than normal lactoferrin or calprotectin level; 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.

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 the Department of Human Services.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional 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, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

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.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. **Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, AND
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during 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.

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, 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, if relevant; or
  - (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
  - (iii) the date of clinical assessment; and
- (iv) the details of prior biological medicine treatment including the 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 the Department of Human Services.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. **Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
- Patient must have confirmed severe 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, AND
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, AND
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or an ostomy patient, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

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

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 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 if relevant; and
  - (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - (iii) the date of the most recent clinical assessment.

Evidence of intestinal inflammation includes:
- (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; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; 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.

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 the Department of Human Services.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

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.

An assessment of a patient’s response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.
**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe Crohn disease

**Treatment Phase:** Balance of supply

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Note** Authority approval for sufficient therapy to complete the balance of supply 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).

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

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### adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL pen devices

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### ADALIMUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' 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 biological medicines at any one time.
From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine 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 biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reactions of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to 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 biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle. A patient who received PBS-subsidised biological medicine 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 biological medicine 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 under the Initial 3 treatment restriction. A patient who has failed fewer than 3 trials of a biological medicine 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 under the Initial 2 treatment restriction. A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime. How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment. Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

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 conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment. For second and subsequent cycles of PBS-subsidised biological medicine, 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.

(2) Continuing treatment. Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 biological medicine supply. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy. Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

(4) Recommencement of treatment after a 24 months break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient)
Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid 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 may 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 may 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 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 may 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 per day; and/or (iii) sodium aurothiomalate at a dose of at least 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.

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.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive
DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9626
HOBART TAS 7001

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break in biological medicine of less than 24 months)

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid 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 a biological medicine for this condition in this treatment cycle, AND
• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during 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.

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).

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.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.
Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.
An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.
A patient who 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 in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.
If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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

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Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, AND
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, AND
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

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

Active joints are defined as:
(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).

All measures of joint count must be no more than 4 weeks old at the time of this 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.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

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**ADALIMUMAB**

**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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient is not limited to try and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once, and
- once a patient has either failed to demonstrate or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

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 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months);
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).
(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months).

Initial applications for a new patient (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, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.
Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to Services Australia within sufficient time to allow processing.

Abatacept patients:
A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Assessment of the patient’s response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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-biological medicine treatment requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternative biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:
A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:
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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Note 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.

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, 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.

Population criteria:
- Patient must be aged 18 years or older.
- An adequate response to treatment is defined as:
  - an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
  - either of the following:
    (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(s); and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

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 Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9626
HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition 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.

Note Authority approval for sufficient therapy to complete the balance of supply 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).
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### ADALIMUMAB

**Note**

**TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term ‘biological medicine’ 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 PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab or infliximab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab or infliximab while they continue to show a response to therapy.

A patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised adalimumab or infliximab treatment prior to 1 April 2011 is considered to have started their treatment 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 adalimumab or infliximab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 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 medicine therapy for this condition 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 adalimumab or infliximab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab or infliximab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy 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 3 trials or fewer of biological medicine therapy 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 adalimumab or infliximab 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 adalimumab or infliximab therapy in this treatment cycle and wishes to commence such therapy (Initial treatment (new patient or Recomencement of treatment after more than 5 years break in therapy - Initial 1)); or

      ii. a patient has received prior PBS-subsidised (initial or continuing) adalimumab or infliximab therapy and wishes to trial an alternate agent (Initial 2 - Change or recommencement) [further details are under ‘Swapping therapy’ below]; or

      iii. a patient wishes to recommence treatment with adalimumab or infliximab following a break in PBS-subsidised therapy with that agent (Change or Recomencement of treatment after a break in therapy of less than 5 years (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 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 biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

   For subsequent courses of PBS-subsidised adalimumab or infliximab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment cycle.

   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. The second prescription must be written for 2 doses of 40 mg and 2 repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

   **(b) Continuing treatment.**

   Adalimumab patients:

   Following the completion of an initial treatment course with adalimumab, 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 treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

   Infliximab patients:

   For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

   For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

   It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure that an assessment of their response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
uninterrupted supply of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted within 4 weeks of the last dose. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab or infliximab at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(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 submitted with the first authority application for adalimumab or infliximab. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

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

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

### Authority required

**Complex refractory Fistulising Crohn disease**

**Treatment Phase: Initial treatment (new patient or Recomencement of treatment after more than 5 years break in therapy - Initial 1)**

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have 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, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation 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 which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 1 month old at the time of application.

A maximum of 16 weeks of treatment with this drug 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.

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.

It is recommended that an application for continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### Authority required
Complex refractory Fistulising Crohn disease

Treatment Phase: Change or Recommencement of treatment after a break in therapy of less than 5 years (Initial 2)

Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, AND
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy following a minimum of 12 weeks of therapy.

It is recommended that an application for continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for withdrawal of treatment.

Applications for authorisation must be made in writing and must include:
- a completed authority prescription form; and
- a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
  - details of prior biological medicine therapy 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 of treatment with this drug 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.

Note: Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Authority required
Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or Recommencement of treatment after more than 5 years break in therapy ); Initial 2 (Change or Recommencement of treatment after a break in therapy of less than 5 years) - Balance of supply

Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition 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 for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) 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.

Note: Authority approval for sufficient therapy to complete the balance of supply 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).
### ADALUMAB

#### Note

**TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological medicines’ appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient who is receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a ‘treatment cycle’, where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response 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 medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

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) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New Patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) ‘Swapping therapy’ below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that
apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the 4 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity. A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient’s response to the PBS-subsidised treatment.

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 treatments.

(6) Recommencement 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 biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and the patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

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

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

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **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 dermatologist.
- 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 baseline value for this treatment cycle.
- The authority application must be made in writing and must include:
  - (a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including 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 this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- The treatment must be as systemic monotherapy (other than methotrexate), 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 dermatologist.

An adequate response to 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 baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including 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 this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot 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 restrictions, AND
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:
- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply 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).

### ADALIMUMAB

Note: The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab for adult patients with ankylosing spondylitis.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 7 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 December 2020 is considered to start their first cycle as of 1 December 2020.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

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 medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines 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 biological medicines 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 biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks...
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

of therapy.

(b) Continuing treatment.
For the first continuing treatment course of PBS-subsidised biological medicine, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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 biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to treatment at every course of treatment. A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.
Services Australia 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 biological medicine.

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 must be used 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 used to determine response.

Prescribers may provide new baseline measurements any time an ‘Initial treatment’ authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Reannocation of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

**Authority required**

Ankylosing spondylitis

**Treatment Phase: Initial treatment - Initial 1 (new patient)**

**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 PBS-subsidised treatment with a biological medicine for this condition, **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 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, **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 ankylosing spondylitis.

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 includes 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.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during 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 ankylosing spondylitis.

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.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.
An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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.

All measurements provided must be no more than 1 month old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9828
HOBART TAS 7001

Authority required
Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, 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 a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, AND
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, 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 ankylosing spondylitis.

The authority application must be made in writing and must include:
- a completed authority prescription form; and
- a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:
  - a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
  - a completed BASDAI Assessment Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.
Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

 Services Australia
 Complex Drugs
 Reply Paid 9826
 HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) 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 ankylosing spondylitis.

**Note** Authority approval for sufficient therapy to complete the balance of supply 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).

### Adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

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### Adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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**ADALIMUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab or vedolizumab at any one time.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, golimumab, infliximab and vedolizumab only.

From 1 June 2018, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2018 is considered to start their first cycle as of 1 June 2018. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. 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 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 medicine treatment in the most recent cycle to the date of the first application for initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine 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 under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle under the Initial 3 treatment restrictions.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment after 1 June 2018.

1. Initial treatment.

Applications for initial treatment should be made where:

(i) an adult patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) an adult patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or

(iii) an adult patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years); or

(iv) an adult patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab. For the second and subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.


Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 biological medicine supply.

3. Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine treatment is approved, a patient may swap to an alternate biological medicine treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressant therapy.

A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. 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.

4. Recommencement 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 biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the scores of disease severity.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term ‘biological medicine’ appears in the following NOTES and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient follows 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 medicine 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 medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure. A patient who has failed fewer than 3 trials of a biological medicine 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 under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

1. Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under ‘Swapping treatment’ below];
or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab. For the second and subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

**Adalimumab only:**

Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

**Continuing treatment.**

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the continuing treatment restriction 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 PBS subsidy criteria are met.

**Swapping therapy.**

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine 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 these swapping arrangements, it is important that they are assessed for response to every course of treatment.

**Recommencement of treatment after a 5-year break in PBS-subsidised therapy.**

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

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

**Authority required**

**Moderate to severe ulcerative colitis**

**Treatment Phase:** Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**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 consecutive 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 consecutive 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 consecutive 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 followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **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.

Applications for authorisation of change or recommencement treatment must be in writing and must include:

- two completed authority prescription forms; and
- a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(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].

For patients weighing 40 kg or greater, a maximum quantity and number of repeats to provide for an initial 16 weeks course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised.

For patients weighing less than 40 kg, a maximum quantity and number of repeats to provide for an initial 16 weeks of this drug consisting of a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised.

Two completed authority prescriptions must be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription must be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Note At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

Population criteria:
- Patient must be 6 years of age or older.

Applications for authorisation must be in writing and must include:
(a) two completed authority prescription forms; and

December 2020
(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 if relevant; and
(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

Two completed authority prescriptions must be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription must be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted 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 golimumab, infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who 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 in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note At the time of the authority application, medical practitioners should request sufficient quantity for up to 16 weeks of treatment under this restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Moderate to severe ulcerative colitis
Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, 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.

Applications for authorisation must be in writing and must include:
(a) two completed authority prescription forms; 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) the details of prior biological medicine treatment including the details of date and duration of treatment.

For patients weighing 40 kg or greater, a maximum quantity and number of repeats to provide for an initial 16 weeks course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised.

For patients weighing less than 40 kg, a maximum quantity and number of repeats to provide for an initial 16 weeks of this drug consisting of a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14 will be authorised.

Two completed authority prescriptions must be submitted with every initial application for this drug. For patients weighing 40 kg or greater, one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription must be written for 2 doses of 40 mg and 2 repeats.

For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

All tests and assessments should be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.auApplications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Authority required
Moderate to severe ulcerative colitis
Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) 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.
Note Authority approval for sufficient therapy to complete the balance of supply 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).

### ADALIMUMAB

#### Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine.

Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine therapy before they are eligible to commence another cycle (further details are under ‘(5) Recommencement 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 prescription for PBS-subsidised therapy was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

1. Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the...
dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted 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.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the relevant treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine 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 with that biological medicine.

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.

(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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

**Authority required**

**General Pharmaceutical Benefits**

**Severe psoriatic arthritis**

**Treatment Phase: Initial treatment - Initial 1 (new patient)**

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**
- Patient must not have received PBS-subsidised treatment with a biological medicine 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 aged 18 years or older.
- 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(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**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).

**Notes**
- Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au.
- Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos.
- Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during 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.

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 authority application must be made in writing and must include:
1. a completed authorisation prescription form(s); and
2. a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis
Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
• The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
• The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, AND
• The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

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

Major joints are defined as (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).

All measures of joint count and ESR and/or CRP 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition 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 biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient’s response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note**
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**
• Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) 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**
Authority approval for sufficient therapy to complete the balance of supply 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).
### ADALIMUMAB

**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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

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 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of 5 or more months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine therapy is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:
- (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or
- (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

Applications for initial treatment should be made when: a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised biological medicine therapy.

Initial applications for a new patient (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, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to Services Australia within sufficient time to allow processing.

Abatacept patients:
A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may
be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (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 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply. Assessment of the patient’s response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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-biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial new authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

Note Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, 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.

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 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. a completed authority prescription form(s); and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug under this restriction they will not be eligible to continue restriction for PBS application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

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 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:

1. exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose:
2. substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial:
3. exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.
Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.
- 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).
- An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence 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 either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
- To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.
- Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
- 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.

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 biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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General Pharmaceutical Benefits 455
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, AND
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, AND
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, AND
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.
- Major joints are defined as (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).
- All measures of joint count and ESR and/or CRP 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.
- The authority application must be made in writing and must include:
  1. a completed authority prescription form(s); and
  2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.
- It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
- To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.
- Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
- 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 Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPoS) at www.servicesaustralia.gov.au/hpos
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HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
**ADALIMUMAB**

Note **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 medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological medicines’ appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a ‘treatment cycle’, where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

**Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.**

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response 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 medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.**

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) **Initial treatment.**

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 · New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 · Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to try an alternate biological medicine (Initial 2 · Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) ‘Swapping therapy’ below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 · Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.
Grandfather patients (risankizumab only). A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment. When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment. Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the 4 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient may be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy. Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response. Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient’s response to the PBS-subsidised treatment.

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 treatments.

(6) Recomencement 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 biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note**

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

**Note**

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

**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)**

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **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 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, AND

- The treatment must be as systemic monotherapy (other than methotrexate), 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 dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin 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.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

1. 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.

2. 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.

3. 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:

1. A completed authority prescription form(s); and
2. A completed Severe Chronic Plaque Psoriasis 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].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

**Note**

Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Whichever of the above conditions applies, if the treatment is not able to provide a response to treatment within the time frame, the assessment of treatment would need to be revised to ensure the most appropriate treatment is being given.

**Note**

Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

- Services Australia
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase:** Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND

- Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND

- The treatment must be as systemic monotherapy (other than methotrexate), 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 dermatologist.

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 baseline value for this treatment cycle.

An 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, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form 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; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**
• Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
• Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
• The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
• The treatment must be as systemic monotherapy (other than methotrexate), **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 dermatologist.

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(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

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

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase:** Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must 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**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; **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 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; **AND**
- The treatment must be as systemic monotherapy (other than methotrexate); **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 dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin 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.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the 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(s); and

(b) a completed Severe Chronic Plaque Psoriasis 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; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

Note
Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au).

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND
- The treatment must be as systemic monotherapy (other than methotrexate), 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 dermatologist.

An adequate response to 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 baseline values; or
  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An 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, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form 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; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
- The condition must be 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; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, AND
- The treatment must be as systemic monotherapy (other than methotrexate), 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 dermatologist.

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(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes 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.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, AND
- The treatment must be as systemic monotherapy (other than methotrexate), 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).

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

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adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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CERTOLIZUMAB PEGOL

Note Authority approval for sufficient therapy to complete the balance of supply 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).

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months - balance of supply.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less 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 for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more 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.

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

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certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

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CERTOLIZUMAB PEGOL

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab for adult patients with ankylosing spondylitis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 7 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 December 2020 is considered to start their first cycle as of 1 December 2020.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

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 medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines 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 biological medicines 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 biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recomencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recomencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to that biological medicine. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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 biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

Services Australia 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 biological medicine.

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 must be used 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 used to determine response.

Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recomencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Note: Authority approval for sufficient therapy to complete the balance of supply 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).

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) 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 ankylosing spondylitis.

### CERTOLIZUMAB PEGOL

**Note:** Treatment of Adult Patients with Ankylosing Spondylitis

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab for adult patients with ankylosing spondylitis.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 7 biological medicines at any 1 time. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 December 2020 is considered to start their first cycle as of 1 December 2020.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once. 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 medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines 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 biological medicines 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 biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab.

- **Initial treatment.**
  - Applications for initial treatment should be made where:
    - (i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to...
General Pharmaceutical Benefits

commence such therapy (Initial 1 - New patient)
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years). A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.
For the first continuing treatment course of PBS-subsidised biological medicine, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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 biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment. A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.
Services Australia 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 biological medicine. 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 must be used 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 used to determine response. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Authority required
Ankylosing spondylitis
Treatment Phase: Continuing treatment
Clinical criteria:
• Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
• Patient must have demonstrated an adequate response to treatment with this drug, AND
• Patient must not receive more than 24 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 ankylosing spondylitis.
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.
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.

All measurements provided must be no more than 1 month old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note: Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Applications for authority approval for sufficient therapy to complete the balance of supply 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).

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle while they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine.

Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious
infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine therapy before they are eligible to commence another cycle [further details are under ‘(5) Recommencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recomencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recomencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted 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.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient. 

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte
séduction rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
- they have not received PBS-subsidised treatment with that particular biological medicine previously;
- they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

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.

(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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of each biological medicine application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of 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.
- Authority approval for sufficient therapy to complete the balance of supply 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).

### Authority required

#### Severe psoriatic arthritis

**Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply**

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) 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.

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### Certolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

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**CERTOLIZUMAB PEGOL**

**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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

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 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).
(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months).

Initial applications for a new patient (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, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to Services Australia within sufficient time to allow processing.

Abatacept patients:
A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.
- Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within
these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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-biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However, the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may so do without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, 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.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:
  1. a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  2. a reduction in the number of the following 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(s); and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

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 Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition 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.

**Note** Authority approval for sufficient therapy to complete the balance of supply 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).

### CERTOLIZUMAB PEGOL

**Note** TREATMENT OF ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of certolizumab pegol and golimumab for adult patients with non-radiographic axial spondyloarthritis.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to certolizumab pegol and golimumab only. A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show or sustain a response to therapy. A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times (twice with the same biological medicine, once with another biological medicine) within the same treatment cycle, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy 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 3 trials or fewer of biological medicine therapy 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.

How to prescribe PBS-subsidised biological medicine treatment with certolizumab pegol and golimumab:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient);

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years). With the exception of grandfathered patients, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed monthly to complete their current course of treatment to ensure uninterrupted biological medicine supply. Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment in courses of up to 24 weeks provided they continue to sustain an adequate response. A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.

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. A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient’s medical records. For a new patient, the BASDAI score used to determine baseline disease severity 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 must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time that an ‘Initial treatment’ authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement 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 biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Note

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

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, AND
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:
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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

A patient whose most recent course of PBS-subsidised treatment was with rituximab and whose response to 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 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)

Initial applications for a new patient (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, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing requirement for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to Services Australia within sufficient time to allow...
processing.
Abatacept patients:
A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine (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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply. Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine.
(2) Swapping therapy
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.
Abatacept:
A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
Rituximab:
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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction. PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.
(3) Baseline measurements to determine response.
Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Notes:
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must not have received PBS subsidised treatment with a biological medicine for this condition, 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 or 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.
- 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 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.
It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an
application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 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 a break in biological medicine of less than 24 months).

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, 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.
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).

An 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, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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.

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.

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 biological medicine.

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **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.
- Major joints are defined as (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).
- All measures of joint count and ESR and/or CRP 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
1. a completed authority prescription form(s); and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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.

### CERTOLIZUMAB PEGOL

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious
infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine therapy before they are eligible to commence another cycle [further details are under ‘(5) Recomencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime. How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recomencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recomencement of treatment after a break in biological medicine of less than 5 years). (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted 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.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between treatment with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine 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 with that biological medicine.

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.

(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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

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 used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

1. a completed authority prescription form(s); and
2. a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date.
of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis
Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition 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 the balance of supply 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).

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

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**CERTOLIZUMAB PEGOL**

Note **TREATMENT OF ADULT PATIENTS WITH NON-RADIOPHASIC AXIAL SPONDYLOARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of certolizumab pegol and golimumab for adult patients with non-radiographic axial spondyloarthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to certolizumab pegol and golimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show or sustain a response to therapy.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times (twice with the same biological medicine, once with another biological medicine) within the same treatment cycle, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy 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 3 trials or fewer of biological medicine therapy 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.

How to prescribe PBS-subsidised biological medicine treatment with certolizumab pegol and golimumab:

1. **Initial treatment.**
   Applications for initial treatment should be made where:
   
   (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy.
Note

Applications for authorisation under this restriction may be made in re-
Continuation of therapy for those patients exceeding the maximum sub-
csidised therapy of five years (Initial 1 - New patient).

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an
alternate agent (Initial 2 - Change or recommencement of treatment after a break in therapy of less than 5 years) [further
details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised
therapy of less than 5 years (Initial 2 - Change or recommencement of treatment after a break in biological medicine of more than 5
years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of
more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

With the exception of grandfathered patients, a patient must be assessed for response to a course of initial PBS-subsidised
treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior
to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive
up to 24 weeks of continuing treatment with that biological medicine provided they have demonstrated an adequate
response to treatment. The patient remains eligible to receive continuing biological medicine treatment in courses of up to
24 weeks provided they continue to sustain an adequate response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no
later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the
required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless
the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate
biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease
severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program
requirements.

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.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed
treatment with that biological medicine unless the patient has experienced a serious adverse reaction requiring permanent
treatment withdrawal.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical
records.

For a new patient, the BASDAI score used to determine baseline disease severity 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 must be
used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted
and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement 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 biological
medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and
indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score) as for the Initial 1 (New patient)
restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Note

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

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial 1 (New patient), Initial 2 (Change or recommencement of treatment after a break in biological
medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5
years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction
to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or
recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20
weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of
treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment, AND
- The treatment must provide no more than the balance of up to 20 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

Note

Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see
www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of
operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Continuing treatment or Grandfather patient - balance of supply
Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the Continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Grandfathered 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 continuing treatment restriction or the grandfather restriction.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

**Note**
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**
Non-radiographic axial spondyloarthritis

**Treatment Phase: Grandfather treatment**

**Clinical criteria:**
- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 June 2020, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that was relieved by exercise but not rest, prior to initiating non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have had 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, prior to initiating non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have had one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactyliitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); prior to initiating non-PBS subsidised treatment with this drug for this condition, **AND**
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis prior to commencing non-PBS subsidised treatment with this biological medicine, **AND**
- The condition must have been diagnosed as non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, prior to having commenced non-PBS subsidised treatment with this biological medicine, **AND**
- The condition must have been saccroiliitis with active inflammation and/or edema on non-contrast Magnetic Resonance Imaging (MRI) prior to commencing non-PBS subsidised treatment with this biological medicine, **AND**
- The condition must have had presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent) prior to commencing non-PBS subsidised treatment with this biological medicine, **AND**
- The condition must have had BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium) prior to commencing non-PBS subsidised treatment with this biological medicine, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug 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 non-radiographic axial spondyloarthritis.

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 to NSAIDs and must have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition:
- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
- (b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must have been no more than 1 month old at the time of initiating non-PBS subsidised treatment with this biological medicine for this condition. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient’s response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

A Grandfathered patient 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.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Non-radiographic axial spondyloarthritis Grandfathered PBS Authority Application - Supporting Information Form which seeks details of:
(i) a copy of the radiological report confirming the absence of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; and
(ii) a BASDAI score and CRP level that substantiates failure to achieve an adequate response to NSAIDs prior to initiating non-PBS subsidised treatment with this biological medicine for this condition; and
(iii) the MRI report; and
(iv) the NSAIDs trialled, their doses and duration of treatment. If applicable, the reason a higher dose cannot be used where the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information must be included.

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

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**CERTOLIZUMAB PEGOL**

Note **TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab for adult patients with ankylosing spondylitis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 7 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 December 2020 is considered to start their first cycle as of 1 December 2020.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. 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 medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines 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 biological medicines 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 biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks...
of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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 biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment. A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

Services Australia 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 biological medicine. 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 must be used 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 used to determine response.

Prescribers may provide new baseline measurements any time an ‘Initial treatment’ authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

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 PBS-subsidised treatment with a biological medicine for this condition, 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, 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 ankylosing spondylitis.

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 Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
- 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 completed authority prescription form; and
- a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:
  - a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
  - a completed BASDAI Assessment Form; and
  - a completed Exercise Program Self Certification Form included in the supporting information form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition 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 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 ankylosing spondylitis.

The authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.
Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient’s response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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. All measurements provided must be no more than 1 month old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Ankylosing spondylitis

**Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)**

**Clinical criteria:**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **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 a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **AND**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **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 ankylosing spondylitis.

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 includes 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.

An assessment of a patient’s response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.
### CERTOLIZUMAB PEGOL

**Note** TREATMENT OF ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

The following information applies to the prescribing of certolizumab pegol and golimumab for adult patients with non-radiographic axial spondyloarthritis.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to certolizumab pegol and golimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show or sustain a response to therapy.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times (twice with the same biological medicine, once with another biological medicine) within the same treatment cycle, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the next treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy 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 3 trials or fewer of biological medicine therapy in a treatment cycle 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.

How to prescribe PBS-subsidised biological medicine treatment with certolizumab pegol and golimumab:

1. **Initial treatment**.
   
   Applications for initial treatment should be made where:
   
   (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient);
   
   (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or
   
   (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or
   
   (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

   With the exception of grandfathered patients, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

2. **Continuing treatment**.

   For continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

   Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment in courses of up to 24 weeks provided they continue to sustain an adequate response.

   A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

3. **Swapping therapy**.

   Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.

   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.

   A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

4. **Baseline measurements to determine response**.

   A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

   For a new patient, the BASDAI score used to determine baseline disease severity must be measured while the patient is

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receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an ‘Initial treatment’ authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recom mencements 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 biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

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

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 1 (New patient)

Clinical criteria:
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, 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, AND
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uvulitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), AND
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, AND
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, AND
- The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), AND
- The condition must be present of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), AND
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), 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 non-radiographic axial spondyloarthritis.

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 to NSAIDs and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
(b) C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application.

Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Non-radiographic axial spondyloarthritis initial PBS Authority Application - Supporting Information Form which seeks details of:

(i) the radiological report confirming the absence of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; and
(ii) a baseline BASDAI score; and
(iii) a baseline C-reactive protein (CRP) level; and
(iv) a completed Exercise Program Self Certification Form included in the supporting information form; and
(v) the MRI report; and...
(vi) the NSAIDs trialed, their doses and duration of treatment. If applicable, the reason a higher dose cannot be used where the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information must be included.

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

Note: Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, AND
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle, AND
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS-indication twice more in 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 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 non-radiographic axial spondyloarthritis.

An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.

A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of application.

- (a) a CRP measurement no greater than 10 mg per L; or
- (b) a CRP measurement reduced by at least 20% from baseline.

The assessment of the patient’s response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.

BASDAI scores and CRP levels must be documented in the patient’s medical records.

The assessment of the patient’s response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment cycle. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

The following must be provided at the time of application and documented in the patient’s medical records:

- (a) the BASDAI score; and
- (b) the C-reactive protein (CRP) level.

Note: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, AND
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), AND
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, AND
The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, AND
The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), AND
The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), AND
The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), 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 non-radiographic axial spondyloarthritis.

The following must be provided at the time of application and documented in the patient’s medical records:
(a) A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
(b) C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.

If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

The assessment of the patient’s response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Note: Applications for authorisation under this restriction may be made in real-time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HIPoS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**CERTOLIZUMAB PEGOL**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any one time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy
(Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an
alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years)
[further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised
therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in
biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of
more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab,
etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the
dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for
ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment
to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks
of therapy and completed 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.
Grandfather patients (ixekizumab only).
A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues
to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment
will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised
treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements
will only apply for the first treatment cycle.
For the second and subsequent courses, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that
apply to a continuing patient.
Grandfather patients (tofacitinib only).
A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues
to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.
A patient will only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment
will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised
treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements
will only apply for the first treatment cycle.
For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that
apply to a continuing patient.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the month
prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the
Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the
patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has
experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient
is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the
most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.
For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that
an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4
weeks from the completion of the most recent course of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate
biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the
Initial 3 treatment restriction with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed
treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting
in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or
continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug
within the same treatment cycle.
Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time)
providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine 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 with that biological medicine.
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.

(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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9626

HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine 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 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 psoriatic arthritis.

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(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.
An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

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 after a break in biological medicine of less than 5 years)

**Clinical criteria:**
- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition 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 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 psoriatic arthritis.

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 authority application must be made in writing and must include:
- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient’s response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

**Severe psoriatic arthritis**

**Treatment Phase:** Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **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.
- Major joints are defined as (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).
- All measures of joint count and ESR and/or CRP 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
1. a completed authority prescription form(s); and
2. a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition 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 biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient’s response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

### cetolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

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### cetolizumab pegol 200 mg/mL injection, 2 x 1 mL pen devices

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### ETANERCEPT

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine.

Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious
infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine therapy before they are eligible to commence another cycle [further details are under ‘(5) Recomencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recomencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recomencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted 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.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

General Pharmaceutical Benefits 497
sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously;
(ii) they have demonstrated an adequate response to that particular biological medicine 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 with that biological medicine.

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.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

Authority required (STREAMLINED)

9156
Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, 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 subsequent 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 psoriatic arthritis.

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 used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.
**ETANERCEPT**

**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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

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 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

1. How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.
      Applications for initial treatment should be made where:
      (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
      (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or
      (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).
   b. Initial and re-commencement of treatment after a break in biological medicine of more than 24 months
      Applications for continuing treatment should be made where:
      (i) a patient has had a break in therapy of at least 24 months and who has had a response to at least 1 course of treatment with a PBS-subsidised biological medicine while they continue to have a disease flare.
      Where a response assessment is not provided the patient will be deemed to have failed or ceased to respond to treatment.
      Where a response assessment is not provided the patient will be deemed to have failed or ceased to respond to treatment.
      A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

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**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

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patient's weight with no repeats. The second prescription for the subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine (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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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-biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialed for each biological medicine therapy.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed to respond to treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:
A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:
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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.
Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

**Authority required [STREAMLINED]**

**7276**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
Population criteria:
- Patient must be aged 18 years or older.

Clinical criteria:
- 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 for this condition, AND
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

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 measurement of response to the prior course of therapy must be documented in the patient’s medical notes.

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.

### ETANERCEPT

**Note** TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab for adult patients with ankylosing spondylitis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 7 biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 December 2020 is considered to start their first cycle as of 1 December 2020.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

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 medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines 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 biological medicines 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 biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recomencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised

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therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years). A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply. Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to realign 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 biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

Services Australia 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 biological medicine.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and exercise program requirements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response.

Prescribers may provide new baseline measurements any time an ‘Initial treatment’ authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

**Note**

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

**Note**

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

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**Authority required (STREAMLINED)**

9481

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

1. an ESR measurement no greater than 25 mm per hour; or
2. a CRP measurement no greater than 10 mg per L; or
3. 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 used to determine response for all subsequent continuing treatments. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**ETANERCEPT**

**Note**

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term ‘biological medicine’ 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 biological medicines at any one time. From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine 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 biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to 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 biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine 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 biological medicine 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 under the Initial 3 treatment restriction. A patient who has failed fewer than 3 trials of a biological medicine 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 under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

1. **Initial treatment.**

   Applications for initial treatment should be made where:

   (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

   (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or

   (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

   (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

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 conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment. For second and subsequent cycles of PBS-subsidised biological medicine, 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.

(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

(4) Recommencement of treatment after a 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

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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.

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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 biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.
weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note**

Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase:** Continuing Treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, AND
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

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**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

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**ETANEOCEPT**

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a ‘treatment cycle’, where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological...
antineoplastic and immunomodulating agents

treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious
diffusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive
multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a
treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant
continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response 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 medicine therapy before
they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was
approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the
new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more
than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

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) Initial treatment.
An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence
such therapy (Initial 1 - New patient); or
(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of
more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years); or
(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and
wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in
biological medicine of less than 5 years) [further details are under (4) ‘Swapping therapy’ below]; or
(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised
therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in
biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab,
etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28
weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure
uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who
continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather
treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment
will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised
授 treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements
will only apply for the first treatment cycle.
For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that
apply to a continuing patient.

(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after
at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial
treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the 4 weeks
prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to
Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be
deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious
adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient
is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a
patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate
biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater
than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5
years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed
treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

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 treatments.

(6) Recommencement 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 biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note: No increase in the maximum number of repeats may be authorised. Authority applications for increased quantities/ repeats (where relevant) 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).

### Authority required (STREAMLINED)

#### 8887
Severe chronic plaque psoriasis

**Treatment Phase:** Subsequent continuing treatment, whole body

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

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

**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, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes. Determination of response must be based on the PASI assessment of response to the most recent course of 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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

### Authority required (STREAMLINED)

#### 8855
Severe chronic plaque psoriasis

**Treatment Phase:** Subsequent continuing treatment, face, hand, foot

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

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

**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:
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(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 baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes. Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. 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 within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

### ETANERCEPT

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab for adult patients with ankylosing spondylitis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 7 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 December 2020 is considered to start their first cycle as of 1 December 2020.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. 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 medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines 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 biological medicines 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 biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recomencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recomencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of

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up to 24 weeks providing they continue to sustain the response. A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy. 
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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 biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response. 
Services Australia 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 biological medicine. 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 must be used 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 used to determine response. Prescribers may provide new baseline measurements any time an ‘Initial treatment’ authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy. 
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

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

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

**Authority required**

**Ankylosing spondylitis**

**Treatment Phase:** Subsequent continuing treatment

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

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

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.

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.

All measurements provided must be no more than 1 month old at the time of application. Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Ankylosing spondylitis
Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) 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 restrictions.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note
Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

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ETANERCEPT

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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to the same PBS subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

A patient whose most recent course of PBS subsidised treatment was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS subsidised biological medicine therapy after 1 April 2019.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)

Initial applications for a new patient (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, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to Services Australia within sufficient time to allow processing.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial course of treatment with a specific biological medicine (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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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-biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Subsequent continuing treatment

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, 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 subsequent continuing treatment course authorised under this restriction.

Population criteria:
- Patient must be aged 18 years or older.
An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- either of the following:
  (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 must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include:
- (1) a completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

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
- Complex Drugs
- Reply Paid 9826
- HOBBART TAS 7001

Authority required
General Pharmaceutical Benefits

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment - balance of supply

TREATMENT CRITERIA:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

CLINICAL CRITERIA:
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) 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 restrictions.

Note: Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

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

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Note: TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib). A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leuкоencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

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 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019:
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).
(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months).

Initial applications for a new patient (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, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab. Rituximab patients should be assessed for response following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition. Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to Services Australia within sufficient time to allow processing. Abatacept patients: A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific biological medicine (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 biological medicine treatment with the same drug in a subsequent course of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply. Assessment of the patient’s response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy. Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine. (2) Swapping therapy Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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-biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled. A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug. Abatacept: A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. Rituximab: 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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction. PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial the course of an alternate biological medicine may do so without having to have any treatment-free period. (3) Baseline measurements to determine response. Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application. Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

### Authority required
Severe active rheumatoid arthritis

**Treatment Phase:** First Continuing treatment

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older. 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(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. 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 Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
- Services Australia
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

### Authority required
Severe active rheumatoid arthritis

**Treatment Phase:** Continuing treatment - balance of supply

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) 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 restrictions.

**Note**
Authority approval for sufficient therapy to complete the balance of supply 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).

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**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

- **9460X**
  - Max.Qty Packs: 1
  - No. of Rpts: 5
  - Premium $: 1066.67
  - DPMQ $: 41.00
  - MRVSN $: * Brenzys [MK]
  - Brand Name and Manufacturer: * Enbrel [PF]

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

- **8638P**
  - Max.Qty Packs: 2
  - No. of Rpts: 5
  - Premium $: *1066.68
  - DPMQ $: 41.00
  - MRVSN $: Enbrel [PF]

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**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

- **9090K**
  - Max.Qty Packs: 1
  - No. of Rpts: 5
  - Premium $: 1066.67
  - DPMQ $: 41.00
  - MRVSN $: * Brenzys [MK]
  - Brand Name and Manufacturer: * Enbrel [PF]

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**ETANERCEPT**

**Note**
TREATMENT OF ADULT PATIENTS WITH ANKYLOSYING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab for adult patients with ankylosing spondylitis.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 7 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 December 2020 is considered to start their first cycle as of 1 December 2020.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

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 medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines 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 biological medicines 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 biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab

(a) Initial treatment.
- Applications for initial treatment should be made where:
  - (i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)
  - (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or
  - (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or
  - (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
- A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.
- For the first continuing treatment course of PBS-subsidised biological medicine, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.
- Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
- A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless
the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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 biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

Services Australia 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 biological medicine. 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 must be used 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 used to determine response.

Prescribers may provide new baseline measurements any time an ‘Initial treatment’ authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

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

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

**Authority required**

Ankylosing spondylitis

**Treatment Phase:** First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 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 ankylosing spondylitis.

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.

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.

All measurements provided must be no more than 1 month old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.
**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) 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 restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Authority approval for sufficient therapy to complete the balance of supply 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).

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### Etanercept 50 mg/mL injection, 4 x 1 mL pen devices

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<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<td><em>Brenzys [MK]</em></td>
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<td><em>Enbrel [PF]</em></td>
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### Etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

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**ETANERCEPT**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any one time. A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine therapy before they are eligible to commence another cycle [further details are under ‘(5) Recomencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to try an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted 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.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine 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 with that biological medicine. 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.

(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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

**Authority required**

Severe psoriatic arthritis

**Treatment Phase:** Subsequent continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, 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 subsequent 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 psoriatic arthritis.

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 in writing to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient’s response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Authority required**

Severe psoriatic arthritis

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) 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 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 the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### etanercept 50 mg/mL injection, 4 x 1 mL pen devices

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**ETANERCEPT**

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' 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 biological medicines at any one time. From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine 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 biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reactions of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infection or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to 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 biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine 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 biological medicine 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 under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine 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 under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy
(Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).
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 conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.
For second and subsequent cycles of PBS-subsidised biological medicine, 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.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 biological medicine supply.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine 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 biological medicine. 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) Recommencement of treatment after a 24 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid 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 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/d; 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.

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.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid 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 a biological medicine for this condition in this treatment cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during 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.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- either of the following:
  (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).

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.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who 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 in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, AND
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, AND
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.
Active joints are defined as:
(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).

All measures of joint count must be no more than 4 weeks old at the time of this 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.
Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.
This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

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General Pharmaceutical Benefits 525
ETANERCEPT

Note: TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine.

Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain the response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine therapy before they are eligible to commence another cycle [further details are under (5) Recommencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction. This limits the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted 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.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).
A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment beyond 3 times in this treatment cycle with that biological medicine.

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.

(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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

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 used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note: Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note: Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis
Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) 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 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 the balance of supply 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).

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### ETANERCEPT

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient who has PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

On a cycle by cycle basis, a patient must have a response to treatment at the end of the current cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

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) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that

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*NOTE: The relevant Biological Medicine Schedule (BMS) entry should be consulted for PBS-subsidised treatment of psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.*

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apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial treatment course. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the 4 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years, who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

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 treatments.

(6) Recomencement 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 biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

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

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

**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase:** Subsequent continuing treatment, whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**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, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient’s condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note
Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

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

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

**Authority required**
Severe chronic plaque psoriasis

**Treatment Phase: Subsequent continuing treatment, Face, hand, foot**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

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

**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 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 baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient’s condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note**
Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

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

Applications for authority to prescribe should be forwarded to:
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe chronic plaque psoriasis

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot 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 restrictions, AND
- The treatment must be as systemic monotherapy (other than methotrexate).

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

**Treatment criteria:**
- Must be treated by a dermatologist.

**Note**
Authority approval for sufficient therapy to complete the balance of supply 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).

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**ETANERCEPT**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological medicines’ appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a ‘treatment cycle’, where they may try biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response 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 medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

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) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the 4 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

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 treatments.

(6) Recomencement 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 biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

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

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

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition,
  - **AND**
- Patient must have demonstrated an adequate response to treatment with this drug,
  - **AND**
- The treatment must be as systemic monotherapy (other than methotrexate),
  - **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**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, or is sustained at this level, when compared with the baseline value for this treatment cycle.
- The authority application must be made in writing and must include:
  - (a) a completed authority prescription form(s); and
  - (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including 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 this drug.
- It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.
- Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
- 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 within this treatment cycle.
- A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

*Note* Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

*Note* Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition,
  - **AND**
- Patient must have demonstrated an adequate response to treatment with this drug,
  - **AND**
- The treatment must be as systemic monotherapy (other than methotrexate),
  - **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**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 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 baseline values; or
  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this
  treatment cycle.
  The authority application must be made in writing and must include:
  (a) a completed authority prescription form(s); and
  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes
  the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including 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 this drug.
  The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area
  assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no
later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of
 treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to
respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in
the necessity for permanent withdrawal of treatment.
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 within this treatment cycle.
A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-
subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the
Initial 3 treatment restriction.

Note
Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.
Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available
online at the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional
Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply
Clinical criteria:
• Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction
  to complete 24 weeks treatment; OR
• Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot
  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 restrictions,
  AND
• The treatment must be as systemic monotherapy (other than methotrexate).
Treatment criteria:
• Must be treated by a dermatologist.

Note
Authority approval for sufficient therapy to complete the balance of supply 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).

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**ETANERCEPT**

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
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

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 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months).

Initial applications for a new patient (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, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with rituximab for this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to Services Australia within sufficient time to allow processing.

Abatacept patients:

A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most
recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, 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.
- 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 trialed, 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 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 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.
- The authority application must be made in writing and must include:
  - (1) a completed authority prescription form(s); and
  - (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.
- It is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
- To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.
- Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
- 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**

**Biosimilar prescribing policy**

Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

**Note**

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note**

Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs
Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

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

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).

An 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, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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.

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.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological medicine treatment for this condition, treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
- Services Australia
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
• Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, AND
• Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND
• Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, AND
• The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
• The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, AND
• The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

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

Major joints are defined as (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).

All measures of joint count and ESR and/or CRP 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment the application must be accompanied with the assessment of response from the previous course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the previous course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

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 Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Any queries concerning the arrangements to prescribe may be directed to Biosimilar prescribing policy

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9626
HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
• Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note**
Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### ETANERCEPT

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

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

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**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

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#### ETANERCEPT

**Note**
**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine therapy before they are eligible to commence another cycle. Further details are under '(15) Recommencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted 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.

Grandfather patients (ixekizumab only).
A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment. Following the commencement of an initial course of treatment with a specific biological medicine, 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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient must be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions. For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy. Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of no less than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine 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 with that biological medicine.

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.

(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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 5 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

**Severe psoriatic arthritis**

**Treatment Phase:** Initial treatment - Initial 1 (new patient)**

**Clinical criteria:**
- Patient must not have received PBS-subsidised treatment with a biological medicine 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 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 psoriatic arthritis.

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(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001

**Authority required**

**General Pharmaceutical Benefits**
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during 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 psoriatic arthritis.

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 authority application must be made in writing and must include:
- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

- Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

- An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note**

Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

**Note**

Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note**

Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:
- Must be treated by a rheumatologist; **OR**
• Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:
• Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
• Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
• The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
• The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, AND
• The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
• Patient must be aged 18 years or older.
• Major joints are defined as (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).
• All measures of joint count and ESR and/or CRP 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
1. a completed authority prescription form(s); and
2. a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition 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 biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note
Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:
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Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis
Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:
• Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) 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 Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

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

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etanercept 50 mg/mL injection, 4 x 1 mL syringes

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ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab for adult patients with ankylosing spondylitis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 7 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 December 2020 is considered to start their first cycle as of 1 December 2020.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

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 medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines 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 biological medicines 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 biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the...
required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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 biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

Services Australia 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 biological medicine. 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 must be used 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 used to determine response.

Prescribers may provide new baseline measurements any time an 'initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommenement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

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

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

**Authority required**

**Antimicrobial spondylitis**

**Treatment Phase: Initial treatment - Initial 1 (new patient)**

**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 PBS-subsidised treatment with a biological medicine for this condition, 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, 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 ankylosing spondylitis.

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 includes 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.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Biosimilar prescribing policy
Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during 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 ankylosing spondylitis.

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.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.
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.

All measurements provided must be no more than 1 month old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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

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Authority required
Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, 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 a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, AND
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, 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 ankylosing spondylitis.

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 includes 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.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.
**Note** Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients. Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

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**Note** Authorisation approval for sufficient therapy to complete the balance of supply 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).  
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Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**  
Ankylosing spondylitis  
Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply  
Clinical criteria:  
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR  
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR  
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) 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 ankylosing spondylitis.  
**Note** Authority approval for sufficient therapy to complete the balance of supply 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).

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**etanercept 50 mg/mL injection, 4 x 1 mL syringes**  
9085E  
Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer  
1 3 ... 1066.67 41.00 * Brenzys [MK] * Enbrel [PF]

**ETANERCEPT**  
**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS  
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.  
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.  
A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.  
A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may try biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.  
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.  
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infection or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response 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 medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

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) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the 4 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or
have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

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 treatments.

(6) Recomencement 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 biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

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

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

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)
Clinical criteria:
- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, AND
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, 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 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, AND
- The treatment must be as systemic monotherapy (other than methotrexate), 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 dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin 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.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the 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(s); and
(b) a completed Severe Chronic Plaque Psoriasis 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].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

**Note**

Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note**

Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement.

**Note**

Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **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 dermatologist.
- 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 baseline value for this treatment cycle.

  An 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, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

  To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

  Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

  The authority application must be made in writing and must include:

  (a) a completed authority prescription form(s); and
  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form 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; and
  (ii) details of prior biological treatment, including dosage, date and duration of treatment.

  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 within this treatment cycle.
A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** **Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naïve patients.

Encouraging biosimilar prescribing for treatment naïve patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase:** Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **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 dermatologist.

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(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

**Note** **Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naïve patients.

Encouraging biosimilar prescribing for treatment naïve patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

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

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HOBART TAS 7001

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**Authority required**
Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1. Face, hand, foot (new patient)

Clinical criteria:

- Patient must 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.
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, AND.
- Patient must have failed to achieve an adequate response, as demonstrated by a Paoriasis Area and Severity Index (PASI) assessment, to at least 2 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.
- The treatment must be as systemic monotherapy (other than methotrexate), 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 dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin 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.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the 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 Paoriasis 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(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Paoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au).

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, AND
- The treatment must be as systemic monotherapy (other than methotrexate), 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 dermatologist.

An adequate response to 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 baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An 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, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form 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; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Biosimilar prescribing policy Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naïve patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be 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; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **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 dermatologist.
- 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(s); and
  - (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes 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.
- It is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
- To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.
- The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.
- Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
- 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 within this treatment cycle.

**Note**

**Prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

**Clinical criteria:**
- Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply
etanercept 50 mg/mL injection, 4 x 1 mL pen devices
9461Y

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etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack
9037P

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etanercept 50 mg/mL injection, 4 x 1 mL syringes
9091L

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<td>41.00</td>
<td>* Brenzys [MK]</td>
<td>* Enbrel [PF]</td>
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**ETANERCEPT**

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

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

**Authority required**

Severe chronic plaque psoriasis

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.

Treatment criteria:

- Must be treated by a dermatologist.

Population criteria:

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

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.

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 etanercept 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 the 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.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.
Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

**Note** Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Whole body) - balance of first supply

**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.

**Treatment criteria:**
- Must be treated by a dermatologist.

**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.

**Note**
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone to contact 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
Complex Drugs
Reply Paid 9626
HOBART TAS 7001

**Authority required**
Severe chronic plaque psoriasis

**TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLACe 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 PASI 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.

**TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

**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 course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

**Note**

In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

**Note**

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

**TREATMENT PHASE: RE-TREATMENT (WHOLE BODY)**

**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.

Treatment criteria:
   - Must be treated by a dermatologist.

Population criteria:
   - Patient must be under 18 years of age.

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.

A patient is eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include:
   (a) a completed authority prescription form; and
   (b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:
      (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition; and
      (ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.
Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment (Face, hand, foot)

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.

Treatment criteria:

(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.

Treatment criteria:
• Must be treated by a dermatologist.

**Population criteria:**
• Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgment.

**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. 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 the 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; or
  (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 recommence treatment.

**Note**
Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

**Note**
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe chronic plaque psoriasis
**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.

Treatment criteria:

- Must be treated by a dermatologist.

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.

**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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis
Treatment Phase: Initial treatment or Re-treatment (Face, hand, foot) - completion of course

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.

Treatment criteria:

- Must be treated by a dermatologist.

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.

An adequate response to 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.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient's condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient's response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

Note In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

Note The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Re-treatment (Face, hand, foot)
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 requested authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:
(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy;
or
(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:
(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR
(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.
Applications for approval for treatment follow 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.

Treatment criteria:
- Must be treated by a dermatologist.

Population criteria:
- Patient must be under 18 years of age.

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.

A patient is eligible for re-treatment due to disease flare if:
- (i) all subscores are rated moderate to severe or 2 of the 3 subscores are rated severe to very severe; or
- (ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area digrams including the dates of assessment of the patient's condition; and
  - (ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**GOLIMUMAB**

**Note**

**TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab or vedolizumab at any one time.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, golimumab, infliximab and vedolizumab only.

From 1 June 2018, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2018 is considered to start their first cycle as of 1 June 2018. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. 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 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 medicine treatment in the most recent cycle to the date of the first application for initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine 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 under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle under the Initial 3 treatment restrictions.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment after 1 June 2018:

1. **Initial treatment.**

   Applications for initial treatment should be made where:
   
   (i) an adult patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient ); or
   
   (ii) an adult patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
   
   (iii) an adult patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years); or
   
   (iv) an adult patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

   Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

   A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab. For the second and subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

2. **Continuing treatment.**

   Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 biological medicine supply.

3. **Swapping therapy.**

   Once initial treatment with the first PBS-subsidised biological medicine treatment is approved, a patient may swap to an alternate biological medicine treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy.

   A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

   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.

4. **Recommencement 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 biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the scores of disease severity.

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**Schedule of Pharmaceutical Benefits – December 2020**
golimumab 100 mg/mL injection, 1 mL pen device

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<th>DPMP $</th>
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- **GOLIMUB**

**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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

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 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below];

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months);

(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)
Initial applications for a new patient (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 provided to a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Response to treatment must be based on the baseline measurements of the joint count, ESR and/or CRP levels and the joint count (or the prior non-subsidised biological medicine therapy requirement except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of their most recent treatment with a biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the assessment. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient 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 courses of up to 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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-subsidised biological medicine therapy requirement except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:

A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:

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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to the revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the
response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 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.
- 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(s); and
  - (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.
- It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.
- Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
- If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.
- 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 Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note**
Authority approval for sufficient therapy to complete the balance of supply 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).

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**GOLIMUMAB**

**Note**
TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab for adult patients with ankylosing spondylitis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 7 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 December 2020 is considered to start their first cycle as of 1 December 2020.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

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 medicine before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines 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 biological medicines 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 biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab.


   Applications for initial treatment should be made where:

   i. a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)

   ii. a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

   iii. a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or

   iv. a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

   A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.


   For the first continuing treatment course of PBS-subsidised biological medicine, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

   Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

   A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

2. Swapping therapy.

   Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to qualify 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 biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

Services Australia 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 biological medicine.

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 must be used 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 used to determine response.

Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recomencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

**Authority required**

**Ankylosing spondylitis**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 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 ankylosing spondylitis.

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.

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.

All measurements provided must be no more than 1 month old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPoS) at www.servicesaustralia.gov.au/hpos

Or mailed to: Services Australia Complex Drugs
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Reply Paid 9826
HOBART TAS 7001

Authority required

Antineplastic and immunomodulating agents

TREATMENT OF ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of certolizumab pegol and golimumab for adult patients with non-radiographic axial spondyloarthritis. Where the term 'biological medicine' appears in notes and restrictions, it refers to certolizumab pegol and golimumab only. A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show or sustain a response to therapy. A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure. Within the same treatment cycle, a patient cannot fail trial or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times (twice with the same biological medicine, once with another biological medicine) within the same treatment cycle, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle. A patient who has failed fewer than 3 trials of biological medicine therapy 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 3 trials or fewer of biological medicine therapy 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.

How to prescribe PBS-subsidised biological medicine treatment with certolizumab pegol and golimumab:

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient);

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years). With the exception of grandfathered patients, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(2) Continuing treatment.

For continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply. Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment in courses of up to 24 weeks provided they continue to sustain an adequate response. A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no...
later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.

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.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

(4) Baseline measurements to determine response.

A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.

For a new patient, the BASDAI score used to determine baseline disease severity 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 must be used for all subsequent continuing treatment applications.

Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement 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 biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

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

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

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### Authority required

Non-radiographic axial spondyloarthritis

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- The treatment must not exceed a maximum of 24 weeks with this drug per authorised course 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 non-radiographic axial spondyloarthritis.

An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:

- (a) a CRP measurement no greater than 10 mg per L; or
- (b) a CRP measurement reduced by at least 20% from baseline.

If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

### Authority required

Non-radiographic axial spondyloarthritis

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug 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.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

### golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

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**GOLIMUMAB**

**Note**

**TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS subsidised treatment with either adalimumab, golimumab, infliximab or vedolizumab at any one time.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, golimumab, infliximab and vedolizumab only.

From 1 June 2018, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS subsidised biological medicine treatment prior to 1 June 2018 is considered to start their first cycle as of 1 June 2018. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS subsidised biological medicine more than once. 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 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 medicine treatment in the most recent cycle to the date of the first application for initial treatment with a PBS subsidised biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infliximab or vedolizumab related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine 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 under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle under the Initial 3 treatment restrictions.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS subsidised biological medicine treatment after 1 June 2018:

1. **Initial treatment.**
   - Applications for initial treatment should be made where:
     - (i) an adult patient has not received prior PBS subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient);
     - (ii) an adult patient has received prior PBS subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or
     - (iii) an adult patient wishes to recommence treatment with a specific biological medicine following a break in PBS subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years); or
     - (iv) an adult patient wishes to recommence treatment with a biological medicine following a break in PBS subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

   Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

   A patient must be assessed for response to a course of initial PBS subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab. For the second and subsequent courses of PBS subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

2. **Continuing treatment.**
   - Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 biological medicine supply.

3. **Swapping therapy.**
   - Once initial treatment with the first PBS subsidised biological medicine treatment is approved, a patient may swap to an alternate biological medicine treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy.

   A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

   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.

4. **Recommencement 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 biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the scores of disease severity.
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

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

**Note**
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au.

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**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 consecutive 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 consecutive 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 consecutive 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 prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; 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).

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

Application 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 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].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is a
decision of adequacy of response to be demonstrated.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
• Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:
• Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, AND
• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

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

Application for authorisation must be made 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 calculation sheet including the date of assessment of the patient's condition if relevant; and
(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (8 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who 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 in this treatment cycle. A patient may re-apply for this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:
• Must be treated by a gastroenterologist (code 87); OR
• Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
• Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:
• Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
• Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition. AND
• Patient must have a Mayo clinic score greater than or equal to 6; 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).

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

Application for authorisation must be made 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 calculation sheet including the date of assessment of the patient's condition if relevant; and
(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum of 14 weeks of treatment with this drug will be approved under this criterion. A loading dose of 200 mg at week 0 and a dose of 100 mg at weeks 2, 6 and 10.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.
An application for a patient who has received PBS-subsidised biological medicine treatment for this condition 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 biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient’s response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

**GOLIMUMAB**

Note: **TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial 1 biological medicine without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine therapy before they are eligible to commence another cycle [further details are under ‘(5) Recommencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction. A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment.

### Golimumab 100 mg/mL injection, 1 mL pen device

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**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**
to ensure uninterrupted biological medicine supply. A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted 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.

Grandfather patients (ixekizumab only).
A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).
A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine (including re-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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to re-qualify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine 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 with that biological medicine.

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.

(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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant
restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

**Authority required**
Severe psoriatic arthritis

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

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

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 used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

1. a completed authority prescription form(s); and
2. a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe psoriatic arthritis

**Treatment Phase:** Continuing treatment - balance of supply

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug for this condition 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
**GOLIMUMAB**

**Note: Treatment of Adult Patients with Moderate to Severe Ulcerative Colitis**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, golimumab, infliximab and vedolizumab for adult patients with ulcerative colitis. Patients are eligible for PBS-subsidised treatment with either adalimumab, golimumab, infliximab or vedolizumab at any one time.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, golimumab, infliximab and vedolizumab only.

From 1 June 2018, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2018 is considered to start their first cycle as of 1 June 2018. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. 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 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 medicine treatment in the most recent cycle to the date of the first application for initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine 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 under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restrictions.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment after 1 June 2018.**

1. **Initial treatment.**

   Applications for initial treatment should be made where:

   (i) an adult patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

   (ii) an adult patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or

   (iii) an adult patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years); or

   (iv) an adult patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

   Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for golimumab, infliximab and vedolizumab.

   A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab. For the second and subsequent courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

2. **Continuing treatment.**

   Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 biological medicine supply.

3. **Swapping therapy.**

   Following the completion of an initial treatment with the first PBS-subsidised biological medicine treatment is approved, a patient may swap to an alternate biological medicine treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy.

   A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy...
(initial or continuing) at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

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.

(4) Recomencement 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 biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the scores of disease severity.

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

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

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with 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.

Population criteria:
- Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 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 sufficient quantity for up to 24 weeks of treatment under this restriction.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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).

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition 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 this restriction.

Note Authority approval for sufficient therapy to complete the balance of supply 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).

Golimumab 100 mg/mL injection, 1 mL pen device

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Golimumab

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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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 inhibitors (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having experienced a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

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 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised treatment with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months); or
(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)

Initial applications for a new patient (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, baricitinib, etanercept, golimumab, tocilizumab, tocافتinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab. Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine.

If a patient receiving PBS-subsidised TNF-alfa antagonist treatment and wishes to commence such therapy, including rituximab, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to Services Australia within sufficient time to allow processing.

Abatacept patients:
A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with the drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate
biological medicine 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-biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine tried.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

**Abatacept:**
A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

**Rituximab:**
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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(3) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 1 (new patient)

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, 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
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

**Antineoplastic and immunomodulating agents**

[587] General Pharmaceutical Benefits

**General**
• Patient must be aged 18 years or older.

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 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) 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 not be 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. a completed authority prescription form(s); and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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
The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, 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.

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).

An 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, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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.

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.

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 biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, AND
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, AND
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, AND
• The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **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.

Major joints are defined as (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).

All measures of joint count and ESR and/or CRP 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
1. a completed authority prescription form(s); and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Authority required

**Severe active rheumatoid arthritis**

**Treatment Phase:** Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply 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).

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| 1                                         | 3             | ..         | 1298.96   | 41.00  |         | Simponi [JC] |
**GOLIMUMAB**

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab for adult patients with ankylosing spondylitis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 7 biological medicines at any 1 time. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 December 2020 is considered to start their first cycle as of 1 December 2020.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. 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 medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines 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 biological medicines 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 biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab.

   (a) Initial treatment.

   Applications for initial treatment should be made where:

   (i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)

   (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or

   (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or

   (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

   A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

   (b) Continuing treatment.

   For the first continuing treatment course of PBS-subsidised biological medicine, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

   Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

   A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

   (2) Swapping therapy.

   Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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 biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment.

   A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

   (3) Baseline measurements to determine response.

   Services Australia 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 biological medicine. For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response.

Prescribers may provide new baseline measurements any time an ‘Initial treatment’ authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

**Authority required**

Ankylosing spondylitis

**Treatment Phase: Initial treatment - Initial 1 (new patient)**

**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 PBS-subsidised treatment with a biological medicine for this condition, **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, **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 ankylosing spondylitis.

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 includes 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.

An assessment of a patient’s response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**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](http://www.humanservices.gov.au)
Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during 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 ankylosing spondylitis.

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.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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.

All measurements provided must be no more than 1 month old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis
Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, 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 a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, AND
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, 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 ankylosing spondylitis.

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 includes 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.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia Complex Drugs Reply Paid 9826
HOBART TAS 7001

Authority required
Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) 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 ankylosing spondylitis.

**Note**
Authority approval for sufficient therapy to complete the balance of supply 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).

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**GOLIMUMAB**

**Note**
TREATMENT OF ADULT PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of certolizumab pegol and golimumab for adult patients with non-radiographic axial spondyloarthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to certolizumab pegol and golimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show or sustain a response to therapy.

A serious adverse reaction requiring permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed or ceased to respond to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

With the exception of grandfathered patients, a patient must be assessed for response to a course of initial PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy 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 3 trials or fewer of biological medicine therapy 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.

How to prescribe PBS-subsidised biological medicine treatment with certolizumab pegol and golimumab:

1) **Initial treatment.**
   Applications for initial treatment should be made where:
   (i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient);
   (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
   (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or
   (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

With the exception of grandfathered patients, a patient must be assessed for response to a course of initial PBS-subsidised biological medicine following a minimum of 12 weeks of therapy.

2) **Continuing treatment.**
   For continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

   Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment in courses of up to 24 weeks provided they continue to sustain an adequate response.

   A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction requiring permanent treatment withdrawal.

3) **Swapping therapy.**
   Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score), or the prior NSAID therapy and exercise program requirements.

   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.

   A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction requiring permanent
treatment withdrawal.
(4) Baseline measurements to determine response.
A response to treatment is based on the baseline BASDAI score and CRP level documented in the patient's medical records.
For a new patient, the BASDAI score used to determine baseline disease severity 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 must be used for all subsequent continuing treatment applications.
Prescribers may provide new baseline measurements any time that an 'Initial treatment' authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
(5) Recomencement 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 biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the C-reactive protein (CRP) level and the BASDAI score) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

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

Authority required
Non-radiographic axial spondyloarthritis
Treatment Phase: Initial treatment - Initial 1 (New patient)

Clinical criteria:
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, 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, AND
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), AND
- The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis, AND
- The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, AND
- The condition must be saccroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), AND
- The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent), AND
- The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), AND
- The treatment must not exceed a maximum of 16 weeks with this drug 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 non-radiographic axial spondyloarthritis.
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 to NSAIDs and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
(b) C-reactive protein (CRP) level greater than 10 mg per L.
The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application.
If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application.
Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) OR a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.
The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Non-radiographic axial spondyloarthritis initial PBS Authority Application - Supporting Information Form which seeks details of:
(i) the radiological report confirming the absence of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; and
(ii) a baseline BASDAI score; and
(iii) a baseline C-reactive protein (CRP) level; and
(iv) a completed Exercise Program Self Certification Form included in the supporting information form; and
(v) the MRI report; and
(vi) the NSAIDs trialed, their doses and duration of treatment. If applicable, the reason a higher dose cannot be used where the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information must be included.

The baseline BASDAI score and CRP level must also be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 2 (Change or re-commencement of treatment after a break of less than 5 years)

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle, **AND**
- The treatment must not exceed a maximum of 16 weeks with this drug 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 non-radiographic axial spondyloarthritis.

Clinical criteria:
- Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS-indication twice or more in the current treatment cycle.
- An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment.
- A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application.
- An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following:
  (a) a CRP measurement no greater than 10 mg per L; or
  (b) a CRP measurement reduced by at least 20% from baseline.
- The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment.
- BASDAI scores and CRP levels must be documented in the patient's medical records.
- The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.
- The following must be provided at the time of application and documented in the patient's medical records:
  (a) the BASDAI score; and
  (b) the C-reactive protein (CRP) level.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest, **AND**
- Patient must have had treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27), **AND**
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

GOLIMUMAB
golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

Note
- Treatment criteria:
  - Must be treated by a rheumatologist; OR
  - Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.
  - The following must be provided at the time of application and documented in the patient's medical records:
    - a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
    - C-reactive protein (CRP) level greater than 10 mg per L.
  - The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.
  - If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application.
  - Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.
  - The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

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 non-radiographic axial spondyloarthritis.
- The following must be provided at the time of application and documented in the patient's medical records:
  - a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and
  - C-reactive protein (CRP) level greater than 10 mg per L.
  - The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.
  - If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application.
  - Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.
  - The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Note
- Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Non-radiographic axial spondyloarthritis
Treatment Phase: Initial 1 (New patient), Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.

Note
- Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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GOLIMUMAB

Note
- TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
  - The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.
  - A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
  - A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine therapy before they are eligible to commence another cycle [further details are under ‘(5) Recomencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime. How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recomencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recomencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted 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.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment was not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the
most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions. For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy. Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine 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 with that biological medicine.

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.

(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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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. A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

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

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

**Authority required**

Severe psoriatic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**
- Patient must not have received PBS-subsidised treatment with a biological medicine 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 aged 18 years or older.
- 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(s); and
(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biologic medicine of less than 5 years)

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:
• Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND
• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during 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.

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 authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a
minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis
Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, AND
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.
- Major joints are defined as (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).
- All measures of joint count and ESR and/or CRP 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition 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 biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note

Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos. Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) 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

Authority approval for sufficient therapy to complete the balance of supply 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).

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

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GUSELKUMAB

Note

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

Note

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

Note

Special Pricing Arrangements apply.

Note

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 medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological medicines’ appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a ‘treatment cycle’, where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response 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 medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

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) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Remcommencement of treatment after a break in biological medicine of more than 5 years); or
(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) ‘Swapping therapy’ below]; or
(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the 4 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that
they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

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 treatments.
(6) Recommencement 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 biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:
- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, AND
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have failed to achieve an adequate response, as demonstrated by a Paediatric Area and Severity Index (PASI) assessment, to at least 2 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/kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg/kg per day for at least 6 weeks, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 20 weeks of treatment under this restriction.

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

Treatment criteria:
- Must be treated by a dermatologist.
Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.
Where intolerance to treatment with phototherapy, methotrexate, cyclosporin 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.
Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:
(a) A current Paediatric Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks 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 4 weeks following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.
The authority application must be in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis 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].
To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
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 within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au)
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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

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Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 20 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

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, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An 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.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form 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; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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

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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 20 weeks of treatment under this restriction.

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

Treatment criteria:
- Must be treated by a dermatologist.
- The most recent PASI assessment must be no more than 4 weeks old at the time of application.
- The authority application must be made in writing and must include:
  (a) a completed authority prescription form(s); and
  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.
- To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.
- Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
- 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 within this treatment cycle.

Note
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Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:
- Patient must 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
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, 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 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, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 20 weeks of treatment under this restriction.

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

Treatment criteria:
- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin 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.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the 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:
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(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 4 weeks 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 4 weeks 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 4 weeks following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis 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; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

Note
Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

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HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 20 weeks of treatment under this restriction.

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

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 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 baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. An 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.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of
biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 PBS Authority Application - Supporting Information Form 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; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9626
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
- The condition must be 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; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 20 weeks of treatment under this restriction.

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

Treatment criteria:
- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes 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.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9626
HOBART TAS 7001
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see further PBS if a patient fails to demonstrate a response to treatment with this drug under this restriction they the necessity for permanent withdrawal of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to enable ongoing treatment for those who meet the continuing restriction for PBS minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. An application for the continuing treatment must be accompanied with the assessment of response conducted following a Approval will be based on the PASI assessment of response to the most recent course of patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Treatment criteria: • Must be treated by a dermatologist. The treatment must be as systemic monotherapy (other than methotrexate), AND The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions. 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, or is sustained at this level, when compared with the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. 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 within this treatment cycle.
A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

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

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 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 baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
guselkumab 100 mg/mL injection, 1 x 1 mL syringe

Note
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**IXEKIZUMAB**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab for adult patients with ankylosing spondylitis.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 7 biological medicines at any 1 time. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 December 2020 is considered to start their first cycle as of 1 December 2020.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

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 medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines 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 biological medicines 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 biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient);
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.
For the first continuing treatment course of PBS-subsidised biological medicine, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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 biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

Services Australia 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 biological medicine.

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 must be used 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 used to determine response.

Prescribers may provide new baseline measurements any time an ‘Initial treatment’ authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

**Note** Special Pricing Arrangements apply.

### Authority required

Ankylosing spondylitis

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 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 ankylosing spondylitis.

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 Form.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 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.

All measurements provided must be no more than 4 weeks old at the time of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

**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 ankylosing spondylitis.

**Note**
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices**

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**IXEKIZUMAB**

**Note**
TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological medicines’ appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a ‘treatment cycle’, where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infuson or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction. Once a patient has either failed or ceased to sustain a response 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 medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

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) Initial treatment.

An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years); or
(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in...
biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of up to 4 years providing they continue to sustain the response. It is recommended that a patient be reviewed the 4 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years, in which case they would need to requalify with respect to the indices of disease severity.

Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

(5) Baseline measurements to determine response.

Baseline PASI assessments will be used to assess the patient's response to the PBS-subsidised treatment on completing treatment. 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 treatments.

(6) Recomencement 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 biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot and soles of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

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

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

Note Special Pricing Arrangements apply.

**Authority required**

Severe chronic plaque psoriasis

**Clinical criteria:**
• Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
• Patient must have demonstrated an adequate response to treatment with this drug, **AND**
• The treatment must be as systemic monotherapy (other than methotrexate), **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 dermatologist.

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 baseline value for this treatment cycle.

The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including 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 this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase:** Continuing treatment, Face, hand, foot

**Clinical criteria:**
• Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
• Patient must have demonstrated an adequate response to treatment with this drug, **AND**
• The treatment must be as systemic monotherapy (other than methotrexate), **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 dermatologist.

An adequate response to 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 baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including 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 this drug.
The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note**
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot 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 restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**
- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply 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).

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### IXEKIZUMAB

**Note** **TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab for adult patients with ankylosing spondylitis.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 7 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 December 2020 is considered to start their first cycle as of 1 December 2020.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

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 medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.
For the first continuing treatment course of PBS-subsidised biological medicine, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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 biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.
Services Australia 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 biological medicine.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and exercise program requirements.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Note: Special Pricing Arrangements apply.

**Authority required**

**Ankylosing spondylitis**

*Treatment Phase: Initial treatment - Initial 1 (new patient)*

**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 PBS-subsidised treatment with a biological medicine for this condition, 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
General Pharmaceutical Benefits

- 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, **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 ankylosing spondylitis.

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 baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be submitted online using the form upload facility in the Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos or mailed to:

Complex Drugs

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

**Authority required**

- Ankylosing spondylitis

**Treatment Phase:** Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during 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 ankylosing spondylitis.

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 Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 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.

All measurements provided must be no more than 4 weeks old at the time of application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9626
HOBART TAS 7001

Authority required
Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:
• Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, AND
• Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition. AND
• The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, 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 a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, AND
• Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
• Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
• Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, 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 ankylosing spondylitis.

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 Form which includes the following:
   (i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
   (ii) a BASDAI score.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note**
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPoS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) 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 ankylosing spondylitis.

**Note**
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices**

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**IXEKIZUMAB**

**Note**
TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a
treatment failure. A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response 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 medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

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) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recom mencement of treatment after a break in biological medicine of more than 5 years); or
(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) ‘Swapping therapy’ below]; or
(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the 4 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological
medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

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 treatments.

(6) Recomencement 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 biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

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

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

**Note** Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Authority required</th>
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<tbody>
<tr>
<td>Severe chronic plaque psoriasis</td>
</tr>
<tr>
<td>Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)</td>
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<tr>
<td><strong>Clinical criteria:</strong></td>
</tr>
<tr>
<td>• Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, <strong>AND</strong></td>
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<tr>
<td>• Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, <strong>AND</strong></td>
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<tr>
<td>• 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 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, <strong>AND</strong></td>
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<tr>
<td>• The treatment must be as systemic monotherapy (other than methotrexate), <strong>AND</strong></td>
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<tr>
<td>• Patient must not receive more than 16 weeks of treatment under this restriction.</td>
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<tr>
<td><strong>Population criteria:</strong></td>
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<td>• Patient must be aged 18 years or older.</td>
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<td>• Must be treated by a dermatologist.</td>
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<td>Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, cyclosporin 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. Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:</td>
</tr>
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<td>(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.</td>
</tr>
<tr>
<td>(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.</td>
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<tr>
<td>(c) The most recent PASI assessment must be no more than 1 month old at the time of application.</td>
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<td>The authority application must be made in writing and must include:</td>
</tr>
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</tr>
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<td>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</td>
</tr>
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<td>(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</td>
</tr>
<tr>
<td>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].</td>
</tr>
<tr>
<td>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</td>
</tr>
</tbody>
</table>

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:
- Patient must have received prior PBS subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS subsidised treatment with this drug for this condition during the current treatment cycle, AND
- The treatment must be as systemic monotherapy (other than methotrexate), 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 dermatologist.

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 baseline value for this treatment cycle.

An 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, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:
- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - details of prior biological treatment, including dosage, date and duration of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)
Clinical criteria:
- Patient must 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
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, 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 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, AND
- The treatment must be as systemic monotherapy (other than methotrexate), 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 dermatologist.
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(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.
It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Note
Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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• Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin 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.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the 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(s); and

(b) a completed Severe Chronic Plaque Psoriasis 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; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

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

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Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

• Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND

• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, AND

• The treatment must be as systemic monotherapy (other than methotrexate), 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 dermatologist.

An adequate response to 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 baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An 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, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, Face, hand, foot (re-ccmencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
- The condition must be 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; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, AND
- The treatment must be as systemic monotherapy (other than methotrexate), 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 dermatologist.

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(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form 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; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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

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Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
- The condition must be 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; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, AND
- The treatment must be as systemic monotherapy (other than methotrexate), 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 dermatologist.

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(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes 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. It is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

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

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Or mailed to:
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Complex Drugs
Reply Paid 9826
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Authority required
Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, AND
- The treatment must be as systemic monotherapy (other than methotrexate), 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).

### IXEKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine therapy before they are eligible to commence another cycle (further details are under (5) Recomencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recomencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recomencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab, secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted 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.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has
experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions. For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine 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 with that biological medicine.

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.

(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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note

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

Note

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

Note

Special Pricing Arrangements apply.

**Authority required**

Severe psoriatic arthritis

**Treatment Phase: Initial treatment - Initial 1 (new patient)**

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine 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 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

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(s); and
2. a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

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

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

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

Authority required
Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, AND
- Patient must not receive more than 20 weeks of treatment under this restriction.

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

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 authority application must be made in writing and must include:

1. a completed authority prescription form(s); and
2. a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.
An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, AND
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, AND
- Patient must not receive more than 20 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (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).

All measures of joint count and ESR and/or CRP 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition 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 biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.
Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note**

Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, AND
- The treatment must provide no more than the balance of up to 20 weeks treatment available under the above restrictions.

**Note**

Authority approval for sufficient therapy to complete the balance of supply 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).

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Grandfather treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 March 2019, AND
- Patient must be receiving treatment with this drug for this condition at the time of application, AND
- Patient must have demonstrated an adequate response following at least 12 weeks of non-PBS-subsidised treatment with this drug 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 prior to initiating non-PBS subsidised treatment with this drug for this condition, 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 prior to initiating non-PBS subsidised treatment with this drug for this condition; 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 prior to initiating non-PBS subsidised treatment with this drug for this condition, AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

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.

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 used to determine response for all subsequent continuing treatments.

The assessment of the patient’s response to this PBS-subsidised course of therapy must be conducted no later than 4 weeks from the cessation of the treatment course.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

A patient 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.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
(3) the date of commencement of this drug; and
(4) results of the baseline patient assessment prior to initiation of non-PBS subsidised therapy with this drug.

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

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

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

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition. **AND**
- Patient must have demonstrated an adequate response to treatment with this drug. **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

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 used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and
(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient’s response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.
Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Authority required

Severe psoriatic arthritis

**Treatment Phase: Continuing treatment or Grandfathered patients - balance of supply**

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Grandfathered 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.

**Note** Authority approval for sufficient therapy to complete the balance of supply 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).

### ixekizumab 80 mg/mL injection, 2 x 1 mL pen devices

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### RISANKIZUMAB

**Note** **TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological medicines’ appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a ‘treatment cycle’, where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response 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 medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

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) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Re-commencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) ‘Swapping therapy’ below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial Treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the 4 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient’s response to the PBS-subsidised treatment.

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 treatments.
(6) Recomencement 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 biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

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

Note No increase in the maximum number of units may be authorised.

Note Special Pricing Arrangements apply.

**Authority required**
Severe chronic plaque psoriasis
Treatment Phase: Continuing treatment, Whole body

**Treatment criteria:**
- Must be treated by a dermatologist.

**Clinical criteria:**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.
- 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 baseline value for this treatment cycle.
  - The authority application must be made in writing and must include:
    - (a) a completed authority prescription form(s); and
    - (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including 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 this drug.
  - It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.
  - Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
  - 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 within this treatment cycle.
  - A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe chronic plaque psoriasis
Treatment Phase: Continuing treatment, Face, hand, foot

**Treatment criteria:**
- Must be treated by a dermatologist.

**Clinical criteria:**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**
• Patient must be aged 18 years or older.

An adequate response to 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 baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including 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 this drug.

The PASI assessment for continued treatment must be performed on the same affected area as assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot or Grandfathered patients - balance of supply

Treatment criteria:
• Must be treated by a dermatologist.

Clinical criteria:
• Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
• Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Grandfathered treatment, Whole body restriction to complete 24 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Grandfathered treatment, Face, hand, foot restriction to complete 24 weeks treatment, AND
• The treatment must be as systemic monotherapy (other than methotrexate), AND
• The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply 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 the balance of supply should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

risankizumab 75 mg/0.83 mL injection, 2 x 0.83 mL syringes

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• **RISANKIZUMAB**

Note **TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological medicines’
appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a ‘treatment cycle’, where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response 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 medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

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) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) ‘Swapping therapy’ below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the 4 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be
deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.
Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

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 treatments.

(6) Recomencement 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 biological therapy of at least 5 years, must qualify under Initial 1 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

**Authority required**
Severe chronic plaque psoriasis

**Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)**

**Treatment criteria:**
- Must be treated by a dermatologist.

**Clinical criteria:**
- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis.
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition.
- 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 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.
- The treatment must be as systemic monotherapy (other than methotrexate).
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.
- Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin 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.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:
- 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.
- 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.
- 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(s); and
(b) a completed Severe Chronic Plaque Psoriasis 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].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

**Note**
Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au).

**Note**
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au.

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos.

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9626
HOBART TAS 7001

### Authority required

**Severe chronic plaque psoriasis**

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**
- Must be treated by a dermatologist.

**Clinical criteria:**
- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

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 baseline value for this treatment cycle.

An 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, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form 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; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**Authority required**
Severe chronic plaque psoriasis

**Treatment Phase:** Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**
- Must be treated by a dermatologist.

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.
- 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(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Treatment criteria:
- Must be treated by a dermatologist.

Clinical criteria:
- Patient must 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
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, 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 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, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.
- Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.
- Where intolerance to treatment with phototherapy, methotrexate, cyclosporin 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.
- Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the 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(s); and
(b) a completed Severe Chronic Plaque Psoriasis 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; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:
- Must be treated by a dermatologist.

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, AND
- The treatment must not be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.
- An adequate response to 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 baseline values; or
  (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An 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, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 PBS Authority Application - Supporting Information Form 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; and
  (ii) details of prior biological treatment, including dosage, date and duration of treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:
- Must be treated by a dermatologist.

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
- The condition must be 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; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

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(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes 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.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment - Whole body, Grandfathered patients

Treatment criteria:
- Must be treated by a dermatologist.

Clinical criteria:
- Patient must have severe chronic plaque psoriasis where lesions had been present for at least 6 months from the time of initial diagnosis prior to initiating non-PBS subsidised treatment, AND
- Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2019, AND
• Patient must have had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with this drug for this condition, **AND**
• Patient must have demonstrated a response to treatment following at least 12 weeks of non-PBS subsidised treatment with this drug for this condition, **AND**
• The treatment must be as systemic monotherapy (other than methotrexate), **AND**
• Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**
• Patient must be aged 18 years or older.

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 baseline value for this treatment cycle.

The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets demonstrating response and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and

The most recent PASI assessment, demonstrating response, must be no more than 1 month old at the time of application.
A Grandfathered patient 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** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment - Face, hand, foot, Grandfathered patients

**Treatment criteria:**
• Must be treated by a dermatologist.

**Clinical criteria:**
• Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where lesions have been present for at least 6 months from the time of initial diagnosis prior to initiating non-PBS subsidised treatment, **AND**
• Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2019, **AND**
• Patient must have had disease, prior to treatment with this drug for this condition, 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 were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot, **AND**
• Patient must have demonstrated a response to treatment following at least 12 weeks of non-PBS subsidised treatment with this drug for this condition, **AND**
• The treatment must be as systemic monotherapy (other than methotrexate), **AND**
• Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**
• Patient must be aged 18 years or older.

An adequate response to 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 baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment must be performed on the same affected area as assessed at baseline or prior to initiation of treatment with this drug.

The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets demonstrating response and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug); and

The most recent PASI assessment, demonstrating response, must be no more than 1 month old at the time of application.
A Grandfathered patient 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**

Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Treatment criteria:**

- Must be treated by a dermatologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

**Note**

Authority approval for sufficient therapy to complete the balance of supply 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 the balance of supply should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826

HOBART TAS 7001

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**risankizumab 75 mg/0.83 mL injection, 2 x 0.83 mL syringes**

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**SECUKINUMAB**

**Note**

TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab for adult patients with ankylosing spondylitis.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 7 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 December 2020 is considered to start their first cycle as of 1 December 2020.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

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 medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines 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 biological medicines 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 biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recomencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recomencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

2. Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to reassess 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 biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

3. Baseline measurements to determine response.

Services Australia 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 biological medicine.

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 must be used 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 used to determine response.

Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

4. Recomencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Note

Authority approval for sufficient therapy to complete the balance of supply 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).

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:
• Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) 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 ankylosing spondylitis.

secukinumab 150 mg/mL injection, 1 mL pen device

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**SECUKINUMAB**

Note

**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 medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological medicines’ appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a ‘treatment cycle’, where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infliximab or injection related reactions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response 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 medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

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. **Initial treatment.**

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); OR

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) ‘Swapping therapy’ below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years). An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).
A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment. When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial treatment course. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment. Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the 4 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy. Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity. A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response. Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient’s response to the PBS-subsidised treatment. 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 treatments.

(6) Recomencement 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 biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note 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).

Authority required
Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, AND
• The treatment must be as systemic monotherapy (other than methotrexate), 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.

#### secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

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### SECUKINUMAB

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab,tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine.

Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine treatment before they are eligible to commence another cycle [further details are under ‘(5) Recommencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the initial application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

**How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.**

1. **Initial treatment.**

   Applications for initial treatment should be made where:

   (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
   (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or
   (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in PBS-subsidised therapy of less than 5 years); or

   (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

   An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for...
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS subsidised treatment must be used to determine response. Similarly, where the baseline active joint count is based on total active joint counts and the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction. The patient remains eligible to receive continuing biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions. For the second and subsequent continuing courses of PBS subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine 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 with that biological medicine.

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.

(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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS subsidised biological medicine must be used 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.
therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Authority approval for sufficient therapy to complete the balance of supply 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).

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<td><strong>Severe psoriatic arthritis</strong></td>
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<tr>
<td>Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply</td>
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<tr>
<td><strong>Clinical criteria:</strong></td>
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<tr>
<td>- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR</td>
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<tr>
<td>- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR</td>
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<tr>
<td>- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment, <strong>AND</strong></td>
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<tr>
<td>- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</td>
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<tr>
<td><strong>Treatment criteria:</strong></td>
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<tr>
<td>- Must be treated by a rheumatologist; OR</td>
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<tr>
<td>- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.</td>
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**SECUKINUMAB 150 mg/mL injection, 1 mL pen device**

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**SECUKINUMAB 150 mg/mL injection, 2 x 1 mL pen devices**

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more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.

(b) Continuing treatment.

For the first continuing treatment course of PBS-subsidised biological medicine, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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 biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

Services Australia 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 biological medicine.

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 must be used 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 used to determine response.

Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 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 ankylosing spondylitis.

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.

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. All measurements provided must be no more than 1 month old at the time of application.
An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Ankylosing spondylitis
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 ankylosing spondylitis.

Note Authority approval for sufficient therapy to complete the balance of supply 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).

secukinumab 150 mg/mL injection, 1 mL pen device

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**SECUKINUMAB**

Note **TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

 Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine therapy before they are eligible to commence another cycle [further details are under ‘(5) Recomencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below];

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years);

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted 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.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
(ii) they have demonstrated an adequate response to that particular biological medicine 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 with that biological medicine.

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.

(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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe psoriatic arthritis

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.
- 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) 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);
      - (ii) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that the patient be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

**Population criteria:**
- Patient must be aged 18 years or older.
- 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) 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);
      - (ii) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that the patient be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
secukinumab 150 mg/mL injection, 1 mL pen device

10895K

Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 752.96 41.00 Cosentyx [NV]

secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

10899P

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1 5 .. 1480.54 41.00 Cosentyx [NV]

§ SECUKINUMB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab for adult patients with ankylosing spondylitis.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 7 biological medicines at any 1 time.

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 December 2020 is considered to start their first cycle as of 1 December 2020.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

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 medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine therapy in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 biological medicines 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 biological medicines 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 biological medicine treatment with adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine treatment in this treatment cycle and wishes to commence such therapy (Initial 1 - New patient)

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same agent (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy.
(b) Continuing treatment.
For the first continuing treatment course of PBS-subsidised biological medicine, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1, Initial 2 or Initial 3 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine it is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be conducted no later than 4 weeks from the cessation of that treatment course. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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 biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 these arrangements, it is important that they are assessed for response to every course of treatment.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.
Services Australia 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 biological medicine. 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 must be used 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 used to determine response.

Prescribers may provide new baseline measurements any time an ‘Initial treatment’ authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must qualify under the Initial 3 treatment restriction. The same clinical criteria and indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI) as for the Initial 1 (New patient) restriction will need to be met, but a re-trial of NSAID therapy and exercise therapy is not required.

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Ankylosing spondylitis
Treatment Phase: Initial treatment - Initial 1 (new patient)

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 PBS-subsidised treatment with a biological medicine for this condition, 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, 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 ankylosing spondylitis.

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 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 includes 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.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au
An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS subsidised treatment.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

- an ESR measurement no greater than 25 mm per hour; or
- a CRP measurement no greater than 10 mg per L; or
- an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

All measurements provided must be no more than 1 month old at the time of application. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

*Antilyosing spondylitis*

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS subsidised biological medicine for this condition, AND
- The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, AND
- Patient must have at least 2 of the following:
  - low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or
  - 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
  - limitation of chest expansion relative to normal values for age and gender, AND
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, AND
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, 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 ankylosing spondylitis.

The authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which includes the following:
  - a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
  - a completed BASDAI Assessment Form.

An assessment of a patient’s response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**secukinumab 150 mg/mL injection, 1 mL pen device**

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<th>DPMQ $</th>
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SEUCINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological medicines’ appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a ‘treatment cycle’, where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reactions of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infections and certain related conditions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response 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 medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

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) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such subsidised treatment (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) ‘Swapping therapy’ below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the 4 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient’s response to the PBS-subsidised treatment.

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 treatments.

(6) Recomencement 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 biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase:** Continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **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 dermatologist.

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 baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including 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 this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **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 dermatologist.

An adequate response to 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 baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including 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 this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**
Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot 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 restrictions, AND
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:
- Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete the balance of supply 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).

**SECUKINUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib, and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine therapy before they are eligible to commence another cycle [further details are under ‘(5) Recommmencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommmencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommmencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommmencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks...
of therapy and conducted 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.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tocilizumab only).

A patient who commenced treatment with Tocilizumab for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(a) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the month prior to completing their current course of treatment to ensure an uninterrupted course of treatment can be supplied.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(iii) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may only trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine 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 with that biological medicine.

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.

(a) 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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.

(i) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.
Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au.

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:
- Patient must not have received PBS-subsidised treatment with a biological medicine 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 aged 18 years or older.
- 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(s); and
- 2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

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 after a break in in biological medicine of less than 5 years)

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:
• Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND
• Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during 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.

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 authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:
• Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
• Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
• The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
• The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, AND
• The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
• Patient must be aged 18 years or older.
Major joints are defined as (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 irreversable damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. a completed authority prescription form(s); and
2. a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition 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 biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

secukinumab 150 mg/mL injection, 1 mL pen device

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secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

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Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological medicines’ appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a ‘treatment cycle’, where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response 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 medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis

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) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the 4 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Grandfather patients (etanercept and etanercept only):

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

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 treatments.
(6) Recommenecement 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 biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Authority required

**Severe chronic plaque psoriasis**

**Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)**

**Clinical criteria:**
- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **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 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, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **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 dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, cyclosporin 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.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the 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(s); and
- (b) a completed Severe Chronic Plaque Psoriasis 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].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.
Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

**Note:** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

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<tr>
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Treatment criteria:
- Must be treated by a dermatologist.

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(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

Authority required
Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:
- Patient must 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
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, 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 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, AND
- The treatment must be as systemic monotherapy (other than methotrexate), 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 dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin 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.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the 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(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

<table>
<thead>
<tr>
<th>Authority required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe chronic plaque psoriasis</td>
</tr>
<tr>
<td>Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)</td>
</tr>
<tr>
<td>Clinical criteria:</td>
</tr>
<tr>
<td>- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, AND</td>
</tr>
<tr>
<td>- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, AND</td>
</tr>
<tr>
<td>- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, AND</td>
</tr>
<tr>
<td>- The treatment must be as systemic monotherapy (other than methotrexate), AND</td>
</tr>
<tr>
<td>- Patient must not receive more than 16 weeks of treatment under this restriction.</td>
</tr>
<tr>
<td>Population criteria:</td>
</tr>
<tr>
<td>- Patient must be aged 18 years or older.</td>
</tr>
<tr>
<td>Treatment criteria:</td>
</tr>
<tr>
<td>- Must be treated by a dermatologist.</td>
</tr>
<tr>
<td>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:</td>
</tr>
<tr>
<td>(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 baseline values; or</td>
</tr>
<tr>
<td>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</td>
</tr>
<tr>
<td>An 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.</td>
</tr>
<tr>
<td>Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</td>
</tr>
<tr>
<td>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</td>
</tr>
<tr>
<td>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</td>
</tr>
<tr>
<td>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</td>
</tr>
<tr>
<td>The authority application must be made in writing and must include:</td>
</tr>
<tr>
<td>(a) a completed authority prescription form(s); and</td>
</tr>
<tr>
<td>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</td>
</tr>
<tr>
<td>(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; and</td>
</tr>
<tr>
<td>(ii) details of prior biological treatment, including dosage, date and duration of treatment.</td>
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<tr>
<td>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 within this treatment cycle.</td>
</tr>
<tr>
<td>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</td>
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**Authority required**
Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)
**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be 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; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **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 dermatologist.

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(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes 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.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

### Secukinumab 150 mg/mL injection, 2 x 1 mL pen devices

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**Tildrakizumab**

Note **TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLACe PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response 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 medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more
than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

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) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) [further details are under (4) ‘Swapping therapy’ below]; or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) ‘Swapping therapy’ below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only):

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the 4 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not withheld where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient’s response to the PBS-subsidised treatment.
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 treatments. 

(6) Recommencement 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 biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase:** Continuing treatment, Whole body

**Clinical criteria:**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

**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, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:
- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under this restriction.

Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase:** Continuing treatment, Face, hand, foot

**Clinical criteria:**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.
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 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 baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PBS assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Treatment criteria:
- Must be treated by a dermatologist.

Note
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tildrakizumab 100 mg/mL injection, 1 mL syringe

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TILDRAKIZUMAB

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological medicines’ appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a ‘treatment cycle’, where
they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the same cycle. A patient has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

The maximum number of treatment cycles a patient may undertake in their lifetime is not limited.

A patient who has failed fewer than 3 biological medicines and who has a break in therapy of more than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

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A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

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A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
(4) Swapping therapy. Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity. A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response. Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient’s response to the PBS-subsidised treatment.

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 treatments.

(6) Recomencement 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 biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note: No increase in the maximum quantity or number of units may be authorised.

Note: No increase in the maximum number of repeats may be authorised.

Note: Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:
- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, AND
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, 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 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, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not have received more than 28 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

Treatment criteria:
- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin 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.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the 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 4 weeks 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 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis 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].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

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, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An 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.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form 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; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

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 within this treatment cycle.
A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase: Initial treatment - Initial 3, Whole body** (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied by the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)**

**Clinical criteria:**

- Patient must 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**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **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 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)
General Pharmaceutical Benefits

Note

Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis
Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin 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.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the 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 4 weeks 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 4 weeks 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 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis 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; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

Note

Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au)

Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Severe chronic plaque psoriasis
Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:
• Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, **AND**

• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**

• The treatment must be as systemic monotherapy (other than methotrexate), **AND**

• Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

• Patient must be aged 18 years or older.

**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 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 baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An 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.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 PBS Authority Application - Supporting Information Form 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; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

• Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

• Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**

• The condition must be 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; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**

• The treatment must be as systemic monotherapy (other than methotrexate), **AND**

• Patient must not receive more than 28 weeks of treatment under this restriction.
Population criteria:
- Patient must be aged 18 years or older.

Treatment criteria:
- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. The authority application must be made in writing and must include:
  (a) a completed authority prescription form(s); and
  (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes 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.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of more than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, AND
- The treatment must be as systemic monotherapy (other than methotrexate), 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 dermatologist.

Note
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**TOCILIZUMAB**

Note **TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term 'biological
medicine' 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 biological medicines at any one time. From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may swap to an alternate biological medicine 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 biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure. Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at minimum, a 12 month break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine 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 biological medicine 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 under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine 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 under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised medicine treatment therapy after 1 April 2014.

(1) Initial treatment.
Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New Patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recomencement of treatment after a break in biological medicine therapy of less than 12 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 12 months with the same medicine (initial 2 - Change or Recomencement of treatment after a break in biological medicine therapy of less than 12 months).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 12 months (initial 3 - Recomencement of treatment after a break in biological medicine of more than 12 months).

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 conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment. For the second and subsequent cycles of PBS-subsidised biological medicine, 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.

(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine 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 joint count submitted with the first authority application for a biological medicine. 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.

(5) Recomencement of treatment after a 12 months break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 12 months, must qualify under the initial 3 restriction and meet the relevant criteria and index of disease severity.

(6) Withdrawal of treatment after sustained remission. Withdrawal of treatment with biological medicine 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

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- Patient must be 30kg or over, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos.

Or mailed to:
Services Australia
**TOCILIZUMAB**

**Note**
- No increase in the maximum number of repeats may be authorised.
- A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.
- Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### Authority required

#### Active giant cell arteritis
- Treatment Phase: Continuing treatment
- **Treatment criteria:**
  - Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis.
- **Clinical criteria:**
  - Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
  - The treatment must not exceed 52 weeks in total including initial and continuing applications.

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### TOCILIZUMAB

**Note**
- Treatment of adult patients with a history of juvenile idiopathic arthritis

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' 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 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine 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 biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leuкоencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to 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 biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine 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 biological medicine 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 under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine 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 under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

1. Initial treatment.

   Applications for initial treatment should be made where:
   - (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
   - (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or
   - (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
   - (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

   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 conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

   For second and subsequent cycles of PBS-subsidised biological medicine, 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.


   Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 an uninterrupted biological medicine supply.

   A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

3. Swapping therapy.

   Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine the patient is ceasing.

   The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a biological medicine. 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. Recom mendation of treatment after a 24 months break in PBS-subsidised therapy.

   A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment
Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, 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.

Population criteria:
- Patient must be aged 18 years or older.
- 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.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note: Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing Treatment - balance of supply

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition 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.
**TOCILIZUMAB**

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.
Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to sustain an adequate response 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 commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) 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 an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - retrial or recommencement of treatment after a break of less than 12 months); or

(iii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - retrial or recommencement of treatment after a break of less than 12 months).

(iv) a patient wishes to recommence treatment following a break in PBS-subsidised tocilizumab therapy of more than 12 months (Initial 3 - recommencement of a new treatment cycle after a break of more than 12 months).

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 conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) 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 this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed in the 4 weeks 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 conducted after a minimum of 12 weeks of treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current treatment course.

(3) 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), 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.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from 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 an adequate 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. Assessment of response according to these revised baseline measurements may then occur. 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 to assess response to the second course.

(5) Recommencement 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 3 treatment restriction.

(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 Services Australia at the time treatment is ceased.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment: Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months) - in a patient of any weight being administered a subcutaneous form of this biological medicine

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply - Continuing treatment in a patient of any weight being administered a subcutaneous form of this biological medicine

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug for this condition 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 therapy available under Continuing treatment.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

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**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

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**TOCILIZUMAB**

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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

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 biological medicines and who has a break in therapy of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (initial 1 - new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months).
(iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)

Initial applications for a new patient (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 will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to Services Australia within sufficient time to allow processing.

Abatacept patients:
A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine (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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

Assessment of the patient's response to treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the cessation of the most recent course of biological medicine therapy.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine.

(2) Swapping therapy
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialed.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:
A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:
In order to trial rituximab, a patient must have trialed 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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.
Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application. Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Severe active rheumatoid arthritis

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **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.

**Population criteria:**
- Patient must be aged 18 years or older.
- 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. Determination of whether a response to treatment has been demonstrated must be based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the eligibility for continuing treatment must be assessed according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used 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 used to determine response.

The authority application must be made in writing and must include:

1. A completed authority prescription form(s); and
2. A completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

**Or mailed to:**

- Services Australia
- Complex Drugs
- Reply Paid 9826
- HOBART TAS 7001

**Authority required**
Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment - balance of supply.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition 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.

Note Authority approval for sufficient therapy to complete the balance of supply 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).

### Tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

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### Tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

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#### TOCILIZUMAB

Caution Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note TREATMENT OF 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:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to sustain an adequate response 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 commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infection or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) 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 an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - retrial or recommencement of treatment after a break of less than 12 months); or

(iii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - retrial or recommencement of treatment after a break of less than 12 months). (iv) a patient wishes to recommence treatment following a break in PBS-subsidised tocilizumab therapy of more than 12 months (Initial 3 - recommencement of a new treatment cycle after a break of more than 12 months).

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 conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) 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 this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed in the 4 weeks 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 conducted after a minimum of 12 weeks of treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current course treatment.

(3) 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), 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.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from 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 an adequate 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. Assessment of response according to these revised baseline measurements may then occur. 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 to assess response to the second course.

(5) Recom mencement 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 3 treatment restriction.

(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 Services Australia at the time treatment is ceased.

Note: Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Systemic juvenile idiopathic arthritis
Treatment Phase: Continuing treatment in a patient weighing at least 30 kg

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must have demonstrated 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 rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

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 C-reactive protein (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.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity 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 Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes 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 4 weeks old at the time of application.

The assessment of the patient’s response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.
The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

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tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

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**TOCILIZUMAB**

**Caution** Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

**Note** No increase in the maximum number or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice

Once a patient has either failed or ceased to sustain an adequate response 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 commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) 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 an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - re-trial or recommencement of treatment after a break of less than 12 months); or

(iii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - re-trial or recommencement of treatment after a break of less than 12 months).

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 conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) 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 this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed in the 4 weeks 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 conducted after a minimum of 12 weeks of treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current treatment course.

(3) 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), except if the patient has had a break in therapy of more than 12 weeks of therapy.
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.
(4) Baseline measurements to determine response.
Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from 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 an adequate 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. Assessment of response according to these revised baseline measurements may then occur. 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 to assess response to the second course.
(5) Recomencement 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 3 treatment restriction.
(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 Services Australia at the time treatment is ceased.

Note: Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Systemic juvenile idiopathic arthritis
Treatment Phase: Continuing treatment in a patient weighing less than 30 kg

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- Patient must have demonstrated 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 rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
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 C-reactive protein (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.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity 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 Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes 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 4 weeks old at the time of application.
The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.
The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.
If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

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Tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices

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### TOCILIZUMAB

**Note**

**TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' 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 biological medicines at any one time. From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine 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 biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to 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 biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine 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 biological medicine 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 under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine 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 under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

1. **Initial treatment.**

   Applications for initial treatment should be made where:

   (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

   (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under ‘Swapping therapy’ below]; or

   (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

   (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

   Initial treatment authorisations will be limited to 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 conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

   For second and subsequent cycles of PBS-subsidised biological medicine, 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.

2. **Continuing treatment.**

   Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 biological medicine supply. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine 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 biological medicine. 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) Recom mencement of treatment after a 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid 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 failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) 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.
- 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 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.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note
The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid 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 a biological medicine for this condition in this treatment cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during 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.
- 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).

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.

Note: Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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HOBART TAS 7001

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, AND
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, AND
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

Active joints are defined as:
(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).

All measures of joint count must be no more than 4 weeks old at the time of this 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.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient’s response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply 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).

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**TOCILIZUMAB**

Caution Inadvertent muscular injection in patients aged less than 12 years may occur with the pen device.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note **TREATMENT OF 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:
  - (i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
  - (ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to sustain an adequate response 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 commence another cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first
application for initial treatment with tocilizumab under the new treatment cycle. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure. How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) 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 an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - retriial or recommencement of treatment after a break of less than 12 months); or
(iii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - retriial or recommencement of treatment after a break of less than 12 months);
(iv) a patient wishes to recommence treatment following a break in PBS-subsidised tocilizumab therapy of more than 12 months (Initial 3 - recommencement of a new treatment cycle after a break of more than 12 months).

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 conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

2) 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 this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed in the 4 weeks 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 conducted after a minimum of 12 weeks of treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab. For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current treatment course.

3) Treatment cycle.
Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient) will be limited to provide for a maximum of 16 weeks of therapy. If 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.

4) Baseline measurements to determine response.
Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from 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 has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Services Australia at the time treatment is ceased.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Systemic juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient weighing at least 30 kg)

Clinical criteria:
• Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, AND
• Patient must have polyarticular course disease which has failed to respond adequately to 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
• Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
• Patient must have 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
• 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 rheumatologist; OR
• Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient 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 of major joints:
   (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 following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and
(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or
(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

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 other treatments 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 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 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.

The assessment of the patient’s response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing at least 30 kg)

Clinical criteria:
• Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, AND
• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during 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 rheumatologist; OR
• Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

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 C-reactive protein (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 application authority 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 which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to re-trial or recommence therapy with this drug, must be accompanied by evidence of a a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Systemic juvenile idiopathic arthritis

**Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months in a patient weighing at least 30 kg)**

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have (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, 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); **OR**
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment 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.

**Population criteria:**

- Patient must be under 18 years of age.

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 which includes the following:
- the date of assessment of severe active systemic juvenile idiopathic arthritis;
- pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition 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 biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.
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:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to sustain an adequate response 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 commence another cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was approved to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusions or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

How to prescribe PBS-subsidised tocilizumab treatment therapy after 1 May 2012.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised tocilizumab treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) 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 an adequate response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2 - re-trial or recommencement of treatment after a break of less than 12 months); or
(iii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2 - re-trial or recommencement of treatment after a break of less than 12 months).

(iv) a patient wishes to recommence treatment following a break in PBS-subsidised tocilizumab therapy of more than 12 months (Initial 3 - recommencement of a new treatment cycle after a break of more than 12 months). Initial treatment autorisations 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 conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) 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 this drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks provided they continue to sustain the response. It is recommended that a patient be reviewed in the 4 weeks 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 conducted after a minimum of 12 weeks of treatment and no later than 4 weeks from the completion of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

For the second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient be assessed for response in the 4 weeks prior to completing their current course of treatment and that an application is posted to Services Australia no later than 2 weeks prior to the patient completing their current treatment course.

(3) 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), 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.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from 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 an adequate 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.
Assessment of response according to these revised baseline measurements may then occur. 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 to assess response to the second course.

(5) Recomencement 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 3 treatment restriction.

(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 Services Australia at the time treatment is ceased.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Systemic juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient weighing less than 30 kg)

Clinical criteria:
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have polyarticular course disease which has failed to respond adequately to 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
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have 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
- 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 rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient 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 of major joints:
   (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 following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and
(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or
(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

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 other treatments 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 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 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.

The assessment of the patient’s response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months in a patient weighing less than 30 kg)

**Clinical criteria:**
- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during 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 rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

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 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).

   (iii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

   (iii) 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).

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 which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retrial or recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient’s response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of a new treatment cycle after a break of more than 12 months in a patient weighing less than 30 kg)

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have (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, 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); **OR**
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment 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.

**Population criteria:**
- Patient must be under 18 years of age.

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 which includes the following:
(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
(ii) pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition 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 biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes**

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**tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL pen devices**

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### TOCILIZUMAB

**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 medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine 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), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines 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 biological medicine therapy may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term PBS-subsidised biological medicine while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine 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 biological medicines for the treatment of rheumatoid arthritis.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

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 biological medicines and who has a break in treatment of less than 24 months may commence a further course of treatment with a biological medicine under Initial 2 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has had a break in therapy of longer than 24 months may commence a further course of treatment with a biological medicine under the Initial 3 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine treatment is stopped to the date of the new application for treatment with a biological medicine.

(1) How to prescribe PBS-subsidised biological medicine therapy after 1 April 2019.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised biological medicine treatment and wishes to commence such therapy, excluding rituximab (Initial 1 - new patient); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2 - change or re-commencement of treatment after a break in biological medicine of less than 24 months [further details are under 'Swapping therapy' below]); or
(iv) a patient has a break in therapy of less than 24 months may commence a further course of treatment with a biological medicine after a break in biological medicine of less than 24 months.
medicine of less than 24 months). (iv) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - re-commencement of treatment after a break in biological medicine of more than 24 months)

Initial applications for a new patient (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, baricitinib, etanercept, golimumab, tocilizumab, tofacitinib and upadacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

Rituximab patients should be assessed following a minimum of 12 weeks after the first infusion, and the assessment should be submitted to Services Australia within 4 weeks to ensure continuity of treatment for those who meet the continuing restriction for PBS subsidised treatment with this drug for this condition.

Where a response assessment is not provided the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment and that where required an application is submitted to Services Australia within sufficient time to allow processing.

Abatacept patients:
A patient is eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. 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 subcutaneous formulation, 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 Services Australia within sufficient time to allow processing. New baselines may be submitted with this application if appropriate.

Rituximab patients:
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:
A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:
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 be assessed for response to every course of treatment, within the timeframes specified in the relevant restriction. PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological medicine 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 medicine therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate biological medicine may do so without having to have any treatment-free period.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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- biological medicine therapy requirements except if the patient has had a break in therapy of more than 24 months who would need to requalify with respect to the indices of disease severity. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled for each PBS subsidised biological medicine.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent, unless they have experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug.

Abatacept:
A patient swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:
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.
used 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 used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient 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. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for re-commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase: Initial treatment - Initial 1 (new patient)**

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **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) lefunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) lefunomide 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, lefunomide 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.

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 dosages 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 following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- A升高 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) 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9626
HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

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).

An 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, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.
Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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.

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.

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 biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (re-commencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Major joints are defined as (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).

All measures of joint count and ESR and/or CRP 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. a completed authority prescription form(s); and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

It is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
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Complex Drugs
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HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply 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).

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TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term 'biological medicine' 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 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may swap to an alternative biological medicine 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 biological medicine while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to 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 medicine therapy before they are eligible to commence another cycle.

The term "treatment break" is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment restriction.

A patient who received PBS-subsidised biological medicine 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 biological medicine 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 under the Initial 3 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine 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 under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle under the Initial 3 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment therapy after 1 April 2014.

(1) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 12 months with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine therapy of less than 12 months).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 12 months (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 12 months).

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 conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

For the second and subsequent cycles of PBS-subsidised biological medicine, 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.

(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 biological medicine supply.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine 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 biological medicine should be accompanied by the approved authority prescription or remaining repeats for the biological medicine 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 joint count submitted with the first authority application for a biological medicine. 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.

(5) Recommencement of treatment after a 12 months break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 12 months, must qualify under the initial 3 restriction and meet the relevant criteria and index of disease severity.

(6) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:
- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:
• Must be treated by a paediatric rheumatologist; OR
• Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:
• Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, AND
• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current 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

Population criteria:
• Patient must be under 18 years of age.

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.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

An assessment of a patient’s response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note
Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note
Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:
• Must be treated by a paediatric rheumatologist; OR
• Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:
• Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, AND
• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current 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

Population criteria:
• Patient must be under 18 years of age.

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.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

An assessment of a patient’s response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note
Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:
• Must be treated by a paediatric rheumatologist; OR
• Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:
• Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, AND
• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current 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
Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

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.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence treatment with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient’s response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who 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 in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications are approved online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints.

Active joints are defined as:

- (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).

All measures of joint count must be no more than 4 weeks old at the time of this application.

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 active joints, the response must be demonstrated on the total number of active joints.

Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction.

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.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition 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 biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:
- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 16 or 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 or 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 or 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions for patients 30 kg or over; OR
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions for patients under 30 kg.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- Patient must be under 30kg, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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).
Tofacitinib and ustekinumab for adult patients with severe active psoriatic arthritis. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological
treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infarction or injection reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine therapy before they are eligible to commence another cycle [further details are under ‘(5) Recomencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below];

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted 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.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

[Further details are under ‘Swapping therapy’ below].

General
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity. A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle. Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

1. they have not received PBS-subsidised treatment with that particular biological medicine previously; or
2. they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
3. they have not previously failed to respond to treatment 3 times in this treatment cycle with that biological medicine.

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.

(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 medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required
Severe psoriatic arthritis
Treatment Phase: Continuing treatment

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

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 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
  - a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The authority application must be made in writing and must include:
1. a completed authority prescription form(s); and
2. a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12...
weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis
Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition 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 the balance of supply 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).

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**USTEKINUMAB**

Note **TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only. A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019. A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure. A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction. Once a patient has either failed or ceased to sustain a response 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 medicine therapy before they are eligible to commence the next cycle. The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was
approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

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) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 5 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the 4 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

Services 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 medicine. However, prescribers may provide new
Note

No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

**Authority required**

Severe chronic plaque psoriasis

**Clinical criteria:**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **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 dermatologist.

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 baseline value for this treatment cycle.

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.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including 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 this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised treatment with this drug was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

**Clinical criteria:**
- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
USTEKINUMAB

**ustekinumab 45 mg/0.5 mL injection, 0.9305 R**

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE**

Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**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 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 baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

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.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including 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 this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase:** Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot 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 restrictions, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply 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).

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**ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

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**USTEKINUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adult patients with severe Crohn disease. Where the term 'biological medicine' appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alpha-antagonists (adalimumab and infliximab), the
alpha-4 beta-7 integrin inhibitor (vedolizumab) and the human IgG1kappa monoclonal antibody (ustekinumab). Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological medicines at any one time.

From 1 September 2017, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised a biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised treatment with a biological medicine prior to 1 September 2017 is considered to have started their treatment cycle as of 1 September 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Once a patient has either failed or ceased to respond to treatment for this condition 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 medicine therapy for this condition 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 medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy 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 may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle.

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, within the timeframes specified in the relevant restriction.
A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(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 CDAI or evidence of intestinal inflammation submitted with the first authority application for a biological medicine. 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.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used to assess response to all subsequent treatments.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A re-\ trial of systemic therapy is not required.

**Authority required**

Severe Crohn disease

**Treatment Phase: Initial treatment - Initial 1 (new patient)**

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be aged 18 years or older.

**Clinical criteria:**

- Patient must have confirmed severe 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, AND
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, AND
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have achieved adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, AND
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction, AND
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

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 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 if relevant; and
   (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
   (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
   (iv) the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least the following:

(a) patient must have evidence of intestinal inflammation;
(b) patient must be assessed clinically as being in a high faecal output state;
(c) patient must be assessed clinically as requiring surgery or total parental nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(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; or
(ii) faeces: higher than normal lactoferrin or calprotectin level; 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.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.
Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional 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, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

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.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity necessitating permanent withdrawal of treatment is not considered as a treatment failure.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity necessitating permanent withdrawal of treatment is not considered as a treatment failure.

Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe Crohn disease

**Treatment Phase:** Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, AND
- Patient must have not failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, AND
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

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, 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, if relevant; or
   (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
   (iii) the date of clinical assessment; and
   (iv) the details of prior biological medicine treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.
A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient’s weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient’s response must have been conducted following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**
- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe 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, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

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 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 if relevant; and
(ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
(iii) the date of the most recent clinical assessment.
Evidence of intestinal inflammation includes:
(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; or
(ii) faeces: higher than normal lactoferrin or calprotectin level; 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 mesentry.
Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.
A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.
Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.
Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.
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.
An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.
Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.
A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe Crohn disease
Treatment Phase: Continuing treatment

Treatment criteria:
• Must be treated by a gastroenterologist (code 87); OR
• Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
• Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:
• Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND
• Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
• Patient must have an adequate response to this drug defined as (a) an 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; or (ii) faeces: normalisation of lactoferrin or calprotectin level; 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), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, AND

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS
• Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

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 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, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

An application 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 conducted 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.

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 the Department of Human Services 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 the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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 quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks.

Where an inadequate number of repeats are requested at the time of the application, medical practitioners should request the appropriate quantity and number of repeats.

The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR

Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, AND

The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment; OR

The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.
**USTEKINUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab for adult patients with severe psoriatic arthritis. Therefore, where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, tofacitinib and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. A patient receiving PBS-subsidised treatment for psoriatic arthritis is able to commence a treatment cycle where they may trial biological medicines without having to experience a disease flare when swapping to the alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab or ustekinumab treatment prior to 1 May 2019 is considered to start their first cycle as of 1 May 2019. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven’s Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has 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 medicine therapy before they are eligible to commence another cycle (further details are under ‘(5) Recommencement 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 prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction. There is no limit to the number of treatment cycles a patient may undertake in their lifetime. How to prescribe PBS-subsidised biological medicine treatment for severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years) or

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, golimumab, secukinumab and tofacitinib, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 20 weeks of therapy for ixekizumab, 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted 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.

Grandfather patients (ixekizumab only).

A patient who commenced treatment with ixekizumab for severe psoriatic arthritis prior to 1 March 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the ‘Grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

Grandfather patients (tofacitinib only).

A patient who commenced treatment with Tofacitinib for severe psoriatic arthritis prior to 1 May 2019 and who continues to...
receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. ‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply. A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1 or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine 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, except if the patient has had a break in therapy of more than 5 years who would need to requalify under the Initial 3 treatment restriction with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within a treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine 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 with that biological medicine.

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.

(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 medicine. However, prescribers may provide new baseline measurements any time that an initial change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

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 used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used 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.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than one month old at the time of application.

Note: No increase in the maximum number of repeats may be authorised.

Note: No increase in the maximum number of units may be authorised.

Note: Special Pricing Arrangements apply.

**Authority required**

Severe psoriatic arthritis

**Treatment Phase:** Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, AND
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- 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 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

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(s); and
(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, AND
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:
• Patient must be aged 18 years or older.
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 authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.
An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to
change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent
course of PBS-subsidised biological medicine treatment, within the timeframes specified below.
Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2,
Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a
minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date
of completion of treatment.
An application for the continuing treatment must be accompanied with the assessment of response following a minimum of
12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date
of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-
subsidised treatment.
Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-
subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for
permanent withdrawal of treatment is not considered as a treatment failure.
A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-
subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the
Initial 3 treatment restriction.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement
for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the
Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700
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HOBART TAS 7001

Authority required
Severe psoriatic arthritis
Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than
5 years)

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:
• Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
• Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological
medicine for this condition, AND
• The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
• The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, AND
• The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least
4 active major joints, AND
• Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:
• Patient must be aged 18 years or older.
Major joints are defined as (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).
All measures of joint count and ESR and/or CRP 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 active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. a completed authority prescription form(s); and
2. a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition 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 biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient’s response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, 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 they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe psoriatic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) 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 restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply 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).

<table>
<thead>
<tr>
<th>USTEKINUMAB</th>
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</thead>
<tbody>
<tr>
<td><strong>Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS</strong></td>
</tr>
<tr>
<td>The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab only.</td>
</tr>
<tr>
<td>A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.</td>
</tr>
<tr>
<td>A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.</td>
</tr>
<tr>
<td>A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a ‘treatment cycle’, where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological</td>
</tr>
</tbody>
</table>

| ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial |
| 10774C |
| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1 | 2 | .. | 3951.07 | 41.00 | Stelara [JC] |
Swapping therapy.

(4) Swapping therapy. is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

Infliximab and etanercept only: adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

deeded to have failed to respond to treatment with that biological medicin

Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response 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 medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines 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 under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

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) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recomencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 22 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient be reviewed in the 4 weeks prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (risankizumab only).

A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to 1 December 2019 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a ‘grandfather’ patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 4 weeks of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, 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 biological medicine 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 the 4 weeks prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment.

(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure patients receive the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

Services 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 medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

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 treatments.

(6) recommencement 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 biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note: No increase in the maximum number of repeats may be authorised.

**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)**

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **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 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 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, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin 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.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A 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(s); and

(b) a completed Severe Chronic Plaque Psoriasis 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].
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. It is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**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, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An 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, Initial 2, Initial 3, or continuing treatment restrictions. It is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form 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; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

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 within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

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.

The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This must ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

**Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)**
Clinical criteria:
- Patient must 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
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, 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 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/kg 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, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

Treatment criteria:
- Must be treated by a dermatologist.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin 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.

Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:
- 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;
- 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.
- The most recent PASI assessment must be no more than 1 month old at the time of application.

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.

The authority application must be made in writing and must include:
- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis 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; and
  (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

Note: Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Applications for authority to prescribe should be submitted online via the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to: Services Australia Complex Drugs
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Authority required
Severe chronic plaque psoriasis
Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:
- Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

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:
- 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 baseline values; or
- a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.
An 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.
Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient’s response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
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.
The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form 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; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.
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 within this treatment cycle.
A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, AND
- The condition must be 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; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, AND
- The treatment must be as systemic monotherapy (other than methotrexate), AND
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:
- Patient must be aged 18 years or older.

Treatment criteria:
- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 1 month old at the time of application.

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.

The authority application must be made in writing and must include:
(a) a completed authority prescription form(s); and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes 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.

It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

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 within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Severe chronic plaque psoriasis

Treatment Phase: Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, AND
- The treatment must be as systemic monotherapy (other than methotrexate), 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 dermatologist.

**Note** Authority approval for sufficient therapy to complete the balance of supply 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).

### ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

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<th>No. of Rpts</th>
<th>Premium $</th>
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### Calcineurin inhibitors

- **CICLOSPORIN**
  - **Caution** Careful monitoring of patients is mandatory.

- **ciclosporin 100 mg/mL oral liquid, 50 mL**
  - **ciclosporin 10 mg capsule, 60**
  - **ciclosporin 100 mg capsule, 30**
  - **ciclosporin 25 mg capsule, 30**
  - **ciclosporin 50 mg capsule, 30**

- **TACROLIMUS**
  - **Caution** Careful monitoring of patients is mandatory.

- **tacrolimus 750 microgram capsule, 100**
  - **tacrolimus 2 mg capsule, 100**
  - **tacrolimus 500 microgram capsule, 100**
  - **tacrolimus 500 microgram modified release capsule, 30**
  - **tacrolimus 1 mg capsule, 100**
  - **tacrolimus 1 mg modified release capsule, 60**
  - **tacrolimus 5 mg capsule, 50**
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

**General Pharmaceutical Benefits**

### TACROLIMUS APOTEX [TX]  
Tacrolimus Sandoz [SZ]

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### Other immunosuppressants

#### AZATHIOPRINE

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<tr>
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#### DIMETHYL FUMARATE

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

10139

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 the sole PBS-subsidised disease modifying therapy for this condition, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, 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 recorded in the patient's medical records.

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<tr>
<th>Brand Name and Manufacturer</th>
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#### DIMETHYL FUMARATE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

10140

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 the sole PBS-subsidised disease modifying therapy for this condition, AND
• Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, 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.

dimethyl fumarate 120 mg enteric capsule, 14

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<th>Max Qty Packs</th>
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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
Patients requiring doses greater than 20 mg per week

methotrexate 10 mg tablet, 50

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**METHOTREXATE**

Note Pharmaceutical benefits that have the form methotrexate Injection 15 mg/0.3 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 15 mg/0.6 mL pre-filled syringe are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

7488
Severe active rheumatoid arthritis
Clinical criteria:
• Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

Authority required (STREAMLINED)

7518
Severe psoriasis
Clinical criteria:
• The condition must not have adequately responded to topical treatment, AND
• Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

methotrexate 15 mg/0.3 mL injection, 0.3 mL syringe

<table>
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<tr>
<th>Max Qty Packs</th>
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<td>89.42</td>
<td>41.00</td>
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methotrexate 15 mg/0.6 mL injection, 4 x 0.6 mL syringes

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<td>* Methoblastin PFS [PF]</td>
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**METHOTREXATE**

Note Pharmaceutical benefits that have the form methotrexate Injection 7.5 mg/0.15 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 7.5 mg/0.3 mL pre-filled syringe are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

7488
Severe active rheumatoid arthritis
Clinical criteria:
• Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

Authority required (STREAMLINED)

7518
Severe psoriasis
Clinical criteria:
• The condition must not have adequately responded to topical treatment, AND
• Patient must be unsuitable for administration of an oral form of methotrexate for this condition.
<table>
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<th>Brand Name and Manufacturer</th>
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<tr>
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<td>Methotrexate Injection 10 mg/0.2 mL pre-filled syringe</td>
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**Note** Pharmaceutical benefits that have the form methotrexate Injection 10 mg/0.2 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 10 mg/0.4 mL pre-filled syringe are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

7488
Severe active rheumatoid arthritis

Clinical criteria:
- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

7518
Severe psoriasis

Clinical criteria:
- The condition must not have adequately responded to topical treatment, AND
- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

**METHOTREXATE**

**METHOTREXATE**

Note Pharmaceutical benefits that have the form methotrexate Injection 20 mg/0.4 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 20 mg/0.8 mL pre-filled syringe are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

7488
Severe active rheumatoid arthritis

Clinical criteria:
- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

7518
Severe psoriasis

Clinical criteria:
- The condition must not have adequately responded to topical treatment, AND
- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.
Severe psoriasis

Clinical criteria:
- The condition must not have adequately responded to topical treatment, AND
- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

methotrexate 25 mg/0.5 mL injection, 0.5 mL syringe

<table>
<thead>
<tr>
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methotrexate 25 mg/mL injection, 4 x 1 mL syringes

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**PIRFENIDONE**

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required
Idiopathic pulmonary fibrosis
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be the sole PBS subsidised treatment for this condition.

Treatment criteria:
- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

pirfenidone 801 mg tablet, 90

<table>
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**PIRFENIDONE**

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required
Idiopathic pulmonary fibrosis
Treatment Phase: Initial treatment 1 - new patient

Clinical criteria:
- The condition must be diagnosed through a multidisciplinary team, AND
- Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, AND
- Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, AND
- Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, AND
- Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, AND
- Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, AND
- The treatment must be the sole PBS subsidised treatment for this condition.

Treatment criteria:
- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.
  A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis.
  Patient must not have an acute respiratory infection at the time of FVC testing.
  Application for authorisation of initial treatment must be in writing and must include:
  a) a completed authority prescription form; and
  b) a completed IPF Authority Application Supporting Information Form; and
  c) a signed patient acknowledgement.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional
Authority required
Idiopathic pulmonary fibrosis
Treatment Phase: Initial treatment 2 - change or re-commencement of treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, AND
- The treatment must be the sole PBS subsidised treatment for this condition.

Treatment criteria:
- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

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).

Authority required
Idiopathic pulmonary fibrosis
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
- The treatment must be the sole PBS subsidised treatment for this condition.

Treatment criteria:
- Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

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).

MUSCULO-SKELETAL SYSTEM

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

Acetic acid derivatives and related substances

DICLOFENAC

diclofenac sodium 100 mg suppository, 20

<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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<td>*28.44</td>
<td>29.73</td>
<td>Voltaren 100 [NV]</td>
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diclofenac sodium 100 mg suppository, 20

<table>
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<tr>
<th>Max Qty Packs</th>
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<td>..</td>
<td>*28.44</td>
<td>29.73</td>
<td>Voltaren 100 [NV]</td>
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DICLOFENAC

Restricted benefit
Chronic arthropathies (including osteoarthritis)

Clinical criteria:
- The condition must have an inflammatory component.

Restricted benefit
Bone pain

Clinical criteria:
- The condition must be due to malignant disease.

diclofenac sodium 50 mg enteric tablet, 50

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MUSCULO-SKELETAL SYSTEM

Schedule of Pharmaceutical Benefits – December 2020

**DICLOFENAC**

**Restricted benefit**
Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**
- The condition must have an inflammatory component.

**Bone pain**
Clinical criteria:
- The condition must be due to malignant disease.

### diclofenac sodium 25 mg enteric tablet, 50

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### diclofenac sodium 25 mg enteric tablet, 50

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**INDOMETACIN**

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### indometacin 100 mg suppository, 20

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**INDOMETACIN**

**Restricted benefit**
Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**
- The condition must have an inflammatory component.

**Bone pain**
Clinical criteria:
- The condition must be due to malignant disease.

### indometacin 25 mg capsule, 50

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**INDOMETACIN**

**Restricted benefit**
Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**
- The condition must have an inflammatory component.

**Bone pain**
Clinical criteria:
- The condition must be due to malignant disease.
### Oxicams

#### MELOXICAM

**Note** Pharmaceutical benefits that have the form meloxicam tablet 7.5 mg and pharmaceutical benefits that have the form meloxicam capsule 7.5 mg are equivalent for the purposes of substitution.

**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.

<table>
<thead>
<tr>
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<tr>
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<td>Clinical criteria:</td>
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<td>• The treatment must be for symptomatic treatment.</td>
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<table>
<thead>
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<th>Restricted benefit</th>
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<td>Clinical criteria:</td>
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<td>• The treatment must be for symptomatic treatment.</td>
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#### meloxicam 7.5 mg capsule, 30

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<tr>
<th>Max Qty Packs</th>
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<tr>
<td></td>
<td></td>
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<td></td>
<td>a-Chem mart Meloxicam [CH]</td>
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<td></td>
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#### meloxicam 7.5 mg tablet, 30

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#### MELOXICAM

**Note** Pharmaceutical benefits that have the form meloxicam tablet 15 mg and pharmaceutical benefits that have the form meloxicam capsule 15 mg are equivalent for the purposes of substitution.

**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.

<table>
<thead>
<tr>
<th>Restricted benefit</th>
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<tr>
<td>Osteoarthritis</td>
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<td>Clinical criteria:</td>
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<td>• The treatment must be for symptomatic treatment.</td>
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<td>Rheumatoid arthritis</td>
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<td>Clinical criteria:</td>
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<td>• The treatment must be for symptomatic treatment.</td>
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#### meloxicam 15 mg capsule, 30

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#### meloxicam 15 mg tablet, 30

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<th>Max Qty Packs</th>
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<td>a-Mobic [BY]</td>
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MUSCULO-SKELETAL SYSTEM

PIROXICAM

Restricted benefit
Chronic arthropathies (including osteoarthritis)

Clinical criteria:
- The condition must have an inflammatory component.

piroxicam 10 mg capsule, 50

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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piroxicam 10 mg capsule, 50

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piroxicam 20 mg capsule, 25

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piroxicam 20 mg capsule, 25

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piroxicam 10 mg dispersible tablet, 50

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piroxicam 20 mg dispersible tablet, 25

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piroxicam 20 mg dispersible tablet, 25

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Propionic acid derivatives

IBUPROFEN

ibuprofen 400 mg tablet, 30

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ibuprofen 400 mg tablet, 30

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IBUPROFEN

Restricted benefit
Bone pain

Clinical criteria:
- The condition must have an inflammatory component.

Drug crossover:
- Mobic [BY]
• The condition must be due to malignant disease.

ibuprofen 400 mg tablet, 30
3190X

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• IBUPROFEN

Restricted benefit
Chronic arthropathies (including osteoarthritis)
Clinical criteria:
• The condition must have an inflammatory component.

ibuprofen 400 mg tablet, 30
5123P

<table>
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<th>Max Qty Packs</th>
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<td>..</td>
<td>..</td>
<td>*17.79</td>
<td>19.08</td>
<td>* APO-Ibuprofen 400 [TX]</td>
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<tr>
<td></td>
<td></td>
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<td>9.00</td>
<td>26.79</td>
<td>* Brufen [GO]</td>
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</table>

• KETOPROFEN

Restricted benefit
Chronic arthropathies (including osteoarthritis)
Clinical criteria:
• The condition must have an inflammatory component.

ketoprofen 200 mg modified release capsule, 28
1590Q

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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ketoprofen 200 mg modified release capsule, 28
5136H

<table>
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<tr>
<td>1</td>
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<td>..</td>
<td>23.05</td>
<td>24.34</td>
<td>* Oruvail SR [AV]</td>
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<tr>
<td></td>
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<td>1.92</td>
<td>24.97</td>
<td>* Orudis SR 200 [SW]</td>
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</table>

• NAPROXEN

Restricted benefit
Chronic arthropathies (including osteoarthritis)
Clinical criteria:
• The condition must have an inflammatory component.

naproxen 1 g modified release tablet, 28
1615B

<table>
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<tr>
<th>Max Qty Packs</th>
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<tr>
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<tr>
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<td>1.12</td>
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naproxen 250 mg tablet, 50
1674D

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naproxen 500 mg tablet, 50
1659H

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naproxen 750 mg modified release tablet, 28
1614Y

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<tr>
<td>1</td>
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<td>1.06</td>
<td>18.00</td>
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• NAPROXEN

Restricted benefit
Chronic arthropathies (including osteoarthritis)
Clinical criteria:
• The condition must be due to malignant disease.
- 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

<table>
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#### NAPROXEN

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**
- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**
- The condition must be due to malignant disease.

### naproxen 1 g modified release tablet, 28

<table>
<thead>
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### naproxen 250 mg tablet, 50

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### naproxen 500 mg tablet, 50

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<td>16.94</td>
<td>18.23</td>
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### naproxen 750 mg modified release tablet, 28

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<tr>
<td></td>
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</table>

#### NAPROXEN

**Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**
- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**
- The condition must be due to malignant disease.

### naproxen sodium 550 mg tablet, 50

<table>
<thead>
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</table>

#### NAPROXEN

**Note** Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**Restricted benefit**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**
- The condition must have an inflammatory component.

**Restricted benefit**

Bone pain

**Clinical criteria:**
- The condition must be due to malignant disease.
### MUSCULO-SKELETAL SYSTEM

#### General Pharmaceutical Benefits

**naproxen sodium 550 mg tablet, 50**

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**Fenamates**

- **MEFENAMIC ACID**
  - Restricted benefit
  - Dysmenorrhoea
  - Restricted benefit
  - Menorrhagia

**mefenamic acid 250 mg capsule, 50**

<table>
<thead>
<tr>
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**Coxibs**

- **CELECOXIB**

  **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.

  - 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.

**celecoxib 100 mg capsule, 60**

<table>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Blooms the Chemist Celecoxib [IB]</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Celebrex [UJ]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Celecoxib APOTEX [TY]</td>
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<td>* Celecoxib GH [GQ]</td>
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<td>* Celexi [RW]</td>
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**celecoxib 200 mg capsule, 30**

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<td>* Celebrex [UJ]</td>
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<td>* Celecoxib APOTEX [TY]</td>
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<td>* Celecoxib GH [GQ]</td>
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<td>* Celexi [RW]</td>
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<td></td>
<td></td>
<td>* GenRx Celecoxib [GX]</td>
</tr>
</tbody>
</table>

**SPECIFIC ANTIRHEUMATIC AGENTS**

#### Quinolines

- **HYDROXYCHLOROQUINE**
  - Authority required (STREAMLINED)
    - 10417
      - Autoimmune disorder
      - Treatment Phase: Initial treatment
    - Clinical criteria:
      - The treatment must be authorised by a medical practitioner who is recognised under State or Territory legislation that forms part of the Health Practitioner Regulation National Law, as a specialist in dermatology, intensive care medicine, paediatrics and child health, physician, or emergency medicine, **AND**
      - Patient must have an autoimmune disorder.
  - Authority required (STREAMLINED)
    - 10418
      - Malaria
      - Treatment Phase: Initial treatment
    - Clinical criteria:
The treatment must be authorised by a medical practitioner who is recognised under State or Territory legislation that forms part of the Health Practitioner Regulation National Law, as a specialist in dermatology, intensive care medicine, paediatrics and child health, physician, or emergency medicine, AND

Patient must require treatment of acute attack; OR

Patient must require suppressive therapy.

### 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.

<table>
<thead>
<tr>
<th>Authority required (STREAMLINED)</th>
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<tr>
<td>Autoimmune disorder</td>
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<tr>
<td>Treatment Phase: Continuing treatment</td>
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**Clinical criteria:** Patient must have previously been treated with PBS-subsidised therapy with this drug for this condition.

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<td>Treatment Phase: Continuing treatment</td>
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**Clinical criteria:** Patient must have previously been treated with PBS-subsidised therapy with this drug for this condition.

### Gold preparations

<table>
<thead>
<tr>
<th>AURANOFIN</th>
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</table>

**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

**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.
MUSCLE RELAXANTS

Muscle relaxants, centrally acting agents

BACLOFEN

Baclofen 10 mg tablet, 100

272P

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer

1 5 .. 22.00 23.29 * APO-Baclofen [TX] * Clofen 10 [AF]

273Q

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer

1 5 .. 33.83 35.12 * APO-Baclofen [TX] * Clofen 25 [AF]

Baclofen 25 mg tablet, 100

MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS

Dantrolene and derivatives

DANTROLENE

Restrictive benefit

Chronic spasticity

dantrolene sodium hemiheptahydrate 25 mg capsule, 100

1779P

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

1 2 .. 122.73 41.00 Dantrium [PF]

Dantrolene sodium hemiheptahydrate 50 mg capsule, 100

1780Q

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

1 2 .. 77.13 41.00 Dantrium [PF]

ANTIGOUT PREPARATIONS

Preparations inhibiting uric acid production

ALLOPURINOL

Note: The dose should be adjusted in accordance with renal function.

allopurinol 100 mg tablet, 200

2600W

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer

1 2 .. 16.88 18.17 * Allopurinol APOTEX [GX] * Allopurinol Sandoz [SZ]

3.47 20.35 18.17 * Zyloprim [RW]

allopurinol 300 mg tablet, 60

2604C

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer

1 2 .. 15.54 16.83 * Allopurinol APOTEX [GX] * Allopurinol Sandoz [SZ]

3.48 19.02 16.83 * Zyloprim [RW]

FEBUXOSTAT

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.

Authority required (STREAMLINED)

8921

Chronic gout

Clinical criteria:

- The condition must be either chronic gouty arthritis or chronic tophaceous gout, AND
- Patient must have a medical contraindication to allopurinol; OR
- Patient must have a documented history of allopurinol hypersensitivity syndrome; OR
- Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.

Febuxostat 80 mg tablet, 28

1044R

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

1 5 .. 51.87 41.00 Adenuric [FK]
PROBENECID

probenecid 500 mg tablet, 100

<table>
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Preparations with no effect on uric acid metabolism

COLCHICINE
colchicine 500 microgram tablet, 30

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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.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit
Osteoporosis

Population criteria:
- Patient must be aged 70 years or older.

Clinical criteria:
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Restricted benefit
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 and zoledronic acid.

IBANDRONATE

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.

Restricted benefit
Bone metastases

Clinical criteria:
- The condition must be due to breast cancer.

<table>
<thead>
<tr>
<th>ibandronate 50 mg tablet, 28</th>
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<tbody>
<tr>
<td>9357L</td>
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### PAMIDRONATE DISODIUM

**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.

**Restricted benefit**
Symptomatic Paget disease of bone

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<thead>
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<th>pamidronate disodium 60 mg/10 mL injection, 10 mL vial</th>
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<tr>
<td>8463K</td>
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<tr>
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</table>

### RISEDRONATE

**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.

**Restricted benefit**
Symptomatic Paget disease of bone

<table>
<thead>
<tr>
<th>risedronate sodium 30 mg tablet, 28</th>
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<tbody>
<tr>
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</tr>
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### 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.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**
Osteoporosis

**Population criteria:**
- Patient must be aged 70 years or older.

**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.

**Note** Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Restricted benefit**
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 and zoledronic acid.

### Risedronate sodium 150 mg tablet, 1

<table>
<thead>
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<th>DPMO</th>
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<td>39.34</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* APO-Risedronate [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td>* Actonel Once-a-Month [TT]</td>
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### Risedronate sodium 35 mg tablet, 4

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<td>36.03</td>
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<td></td>
<td>37.32</td>
<td>* Acris Once-a-Week [AF]</td>
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<td>* Risedro once a week [RW]</td>
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<td>* APO-Risedronate [TX]</td>
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### Risedronate sodium 35 mg enteric tablet, 4

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### Risedronate sodium 5 mg tablet, 28

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<td></td>
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<td>37.32</td>
<td>Actonel [TT]</td>
</tr>
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</table>

### Zoledronic Acid

**Note** Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

### Authority required (STREAMLINED)

#### 5710

- Symptomatic Paget disease of bone
- Only 1 treatment each year per patient will be PBS-subsidised

### Zoledronic acid 5 mg/100 mL injection, 100 mL vial

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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</tr>
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<td></td>
<td></td>
<td></td>
<td>41.00</td>
<td>* Aclasta [HX]</td>
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<td></td>
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<td></td>
<td></td>
<td>* Zoledista [TX]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Osteovan [SZ]</td>
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### Zoledronic acid 5 mg/100 mL injection, 100 mL bag

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<th>DPMO</th>
<th>MRVSN</th>
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<td>..</td>
<td>117.06</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>41.00</td>
<td>* Ostira [PF]</td>
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</table>

### Zoledronic Acid

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

### Authority required (STREAMLINED)

#### 6308

- 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)

#### 6313

- Osteoporosis

**Population criteria:**
- Patient must be aged 70 years or older.

**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.
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)**

### 6318

**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.

**Bisphosphonates, combinations**

- **ALENDRONATE + COLECALCIFEROL**

  **Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Authority required (STREAMLINED)**

### 6306

**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)**

### 6325

**Osteoporosis**

**Population criteria:**
- Patient must be aged 70 years or older.

**Clinical criteria:**
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

### 6319

**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.

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.

### zoledronic acid 5 mg/100 mL injection, 100 mL vial

**9288W**

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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>
<td>..</td>
<td>117.06</td>
<td>41.00</td>
<td>a</td>
<td>Aclasta [HX]</td>
<td>a Osteovan [SZ]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Zoledasta [TX]</td>
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</table>

### zoledronic acid 5 mg/100 mL injection, 100 mL bag

**10555M**

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<tr>
<th>Max Qty Packs</th>
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<tr>
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### alendronate 70 mg + colecalciferol 140 microgram (5600 units) tablet, 4

**9183H**

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<td>a Alendronate plus D3-DRLA [RZ]</td>
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<td>a FonatPlus [AF]</td>
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<td>4.00</td>
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MUSCULO-SKELETAL SYSTEM

### ALENDRONATE + COLECALCIFEROL

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

**Note** Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

---

**Authority required (STREAMLINED)**

#### 6307

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)**

#### 6320

Osteoporosis

**Population criteria:**
- Patient must be aged 70 years or older.

**Clinical criteria:**
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

---

**Authority required (STREAMLINED)**

#### 6315

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.

---

### ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

---

**Authority required (STREAMLINED)**

#### 6306

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)**

#### 6325

Osteoporosis

**Population criteria:**
- Patient must be aged 70 years or older.

**Clinical criteria:**
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.
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.

Alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack

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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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Risedronate (&) Calcium Carbonate

Note: Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

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.

Calcitriol

Authority required (STREAMLINED)

5401 Hypocalcaemia

Clinical criteria:
- The condition must be due to renal disease.

Authority required (STREAMLINED)

5255 Hypoparathyroidism

Authority required (STREAMLINED)

5089
Hypophosphataemic rickets

**Authority required (STREAMLINED)**

5114

Vitamin D-resistant rickets

**Authority required (STREAMLINED)**

5402

Established osteoporosis

**Clinical criteria:**
- Patient must have fracture due to minimal trauma.
- The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient’s medical records when treatment is initiated.
- A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

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</tbody>
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---

**DENOSUMAB**

**Note** Denosumab is not PBS-subsidised for use in patients who have undergone curative surgical resection.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
<thead>
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<th>Denosumab 120 mg/1.7 mL injection, 1.7 mL vial</th>
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<td>10061M</td>
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<tr>
<td>Max Qty Packs No. of Rpts Premium $   DPMQ $   MRVSN $</td>
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<td>1 5</td>
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**DENOSUMAB**

**Note** Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<td>1 5</td>
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**DENOSUMAB**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

<table>
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<tr>
<td>Osteoporosis</td>
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<td><strong>Population criteria:</strong></td>
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**GENEAL**

**Hypophosphataemic rickets**

**Authority required (STREAMLINED)**

5114

**Vitamin D-resistant rickets**

**Authority required (STREAMLINED)**

5402

**Established osteoporosis**

**Clinical criteria:**
- Patient must have fracture due to minimal trauma.
- 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.

<table>
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**DENOSUMAB**

**Note** Denosumab is not PBS-subsidised for use in patients who have undergone curative surgical resection.

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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**DENOSUMAB**

**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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**DENOSUMAB**

**Note** Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.
• Patient must be aged 70 years or older.

Clinical criteria:
• Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND
• Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)
6524
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.

Raloxifene hydrochloride 60 mg tablet, 28

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Note
Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride and zoledronic acid.

Authority required (STREAMLINED)
6314
Established post-menopausal osteoporosis
Clinical criteria:
• Patient must have fracture due to minimal trauma, AND
• Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Raloxifene hydrochloride 60 mg/mL injection, 1 mL syringe

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TERIPARATIDE

Note
No increase in the maximum quantity or number of units may be authorised.
Note
No increase in the maximum number of repeats may be authorised.
Note
Special Pricing Arrangements apply.

Authority required
Severe established osteoporosis
Treatment Phase: Initial treatment

Treatment criteria:
• Must be treated by a specialist; OR
• Must be treated by a consultant physician.

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.

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.
NERVOUS SYSTEM

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 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.

teriparatide 250 microgram/mL injection, 2.4 mL pen device

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NERVOUS SYSTEM

ANALGESICS

OPIOIDS

Natural opium alkaloids

CODEINE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit
Severe pain

Clinical criteria:
- The treatment must be for short term therapy of acute severe pain, AND
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

codeine phosphate hemihydrate 30 mg tablet, 20

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CODEINE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit
Severe pain

Clinical criteria:
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

codeine phosphate hemihydrate 30 mg tablet, 20

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CODEINE

Caution The risk of drug dependence is high.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Severe pain

Clinical criteria:
- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

### CODEINE

**Caution**
The risk of drug dependence is high.

**Note**
Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

**Pharmaceutical Benefits Scheme**
Reply Paid 9857
[Your capital city]

#### Restricted benefit

**Severe pain**
**Treatment Phase:** Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### Restricted benefit

**Severe pain**
**Treatment Phase:** Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; **OR**
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### Restricted benefit

**Severe pain**
**Treatment Phase:** Continuing PBS treatment after 1 June 2020

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.
Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:
(i) severe disabling pain associated with malignant neoplasia; or
(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

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Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**codeine phosphate hemihydrate 30 mg tablet, 20**

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**HYDROMORPHONE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**
Severe pain

**Clinical criteria:**
- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**hydromorphone hydrochloride 2 mg tablet, 20**

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**HYDROMORPHONE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**
Severe pain

**Clinical criteria:**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**hydromorphone hydrochloride 2 mg tablet, 20**

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Hydromorphone hydrochloride 1 mg/mL oral liquid, 200 mL
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**HYDROMORPHONE**

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

**Severe pain**

**Clinical criteria:**

- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Hydromorphone hydrochloride 2 mg tablet, 20
12047C

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Hydromorphone hydrochloride 8 mg tablet, 20
12016K

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</tr>
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</table>

**HYDROMORPHONE**

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to: Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Restricted benefit**

**Severe pain**

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

**Severe pain**

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
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(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

**Treatment Phase: Continuing PBS treatment after 1 June 2020**

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with malignant neoplasia; or
(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### hydromorphone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</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></td>
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</tbody>
</table>

### hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules

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<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>Dilaudid [MF]</td>
<td>1</td>
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<td>27.65</td>
<td>28.94</td>
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</tr>
<tr>
<td>HYDROMORPHONE JUNO [JU]</td>
<td></td>
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### hydromorphone hydrochloride 2 mg tablet, 20

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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### hydromorphone hydrochloride 4 mg tablet, 20

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<th>Brand Name and Manufacturer</th>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<tbody>
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</tbody>
</table>
**HYDROMORPHONE**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-onlinepbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to: Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Authority required (STREAMLINED)**

**10754**

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**
- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

 Authorities requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

**10753**

Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**
- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.
Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

**10752**

**Chronic severe pain**

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.
- Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:
  1. is less than 12 months; or
  2. exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
  3. exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  4. has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.
- Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.
- Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.
- Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

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<table>
<thead>
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<table>
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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.

#### Restricted benefit

Severe pain

**Clinical criteria:**
- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

<table>
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<tbody>
<tr>
<td>12067D Max Qty Packs</td>
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</table>

### MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.
Clinical criteria:
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

**morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
<td>1</td>
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<td>26.50</td>
<td>27.79</td>
<td>Morphone Juno [JU]</td>
<td></td>
</tr>
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</table>

**morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules**

<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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<tbody>
<tr>
<td>1</td>
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<td>24.54</td>
<td>25.83</td>
<td>* DBL Morphine Sulfate Pentahydrate [PF]</td>
<td>* MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ]</td>
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**morphine sulfate pentahydrate 30 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>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>26.64</td>
<td>27.93</td>
<td>* DBL Morphine Sulfate Pentahydrate [PF]</td>
<td>* MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ]</td>
</tr>
</tbody>
</table>

### MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**morphine hydrochloride trihydrate 2 mg/mL oral liquid, 200 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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**morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL**

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>29.94</td>
<td>Ordine 5 [MF]</td>
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**morphine sulfate pentahydrate 30 mg tablet, 20**

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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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**morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL**

<table>
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<tr>
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<th>MRVSN $</th>
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### MORPHINE

**Caution** The risk of drug dependence is high.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe pain

**Clinical criteria:**
- The treatment must be for short term therapy of acute severe pain, AND
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

**morphine sulfate pentahydrate 30 mg tablet, 20**

<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>22.65</td>
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### MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Note** Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.
Severe pain

Clinical criteria:
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

MORPHINE

Caution The risk of drug dependence is high.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-onlinepbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Restricted benefit

Severe pain
Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit

Severe pain
Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats must only be considered for:
(i) severe disabling pain associated with proven malignant neoplasia; or
(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.
Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

**Treatment Phase: Continuing PBS treatment after 1 June 2020**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.
- Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:
  - (i) severe disabling pain associated with malignant neoplasia; or
  - (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
  - (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
  - (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  - (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.
- Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.
- Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.
- Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

### morphine hydrochloride trihydrate 20 mg/mL injection, 5 x 1 mL ampoules

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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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<tr>
<td>10874H</td>
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<td>..</td>
<td>26.50</td>
<td>27.79</td>
<td>Morphine Juno [JU]</td>
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### morphine hydrochloride trihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules

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<th>Max Qty Packs</th>
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### morphine hydrochloride trihydrate 100 mg/5 mL injection, 5 x 5 mL ampoules

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### morphine sulfate pentahydrate 15 mg/mL injection, 5 x 1 mL ampoules

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<td></td>
<td>MORPHINE SULFATE 15 mg/1 mL MEDSURGE [DZ]</td>
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### morphine sulfate pentahydrate 30 mg/mL injection, 5 x 1 mL ampoules

<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>26.64</td>
<td>27.93</td>
<td>DBL Morphine Sulfate Pentahydrate [PF]</td>
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<td></td>
<td></td>
<td></td>
<td>MORPHINE SULFATE 30 mg/1 mL MEDSURGE [DZ]</td>
</tr>
</tbody>
</table>

**MORPHINE**

**Caution**
The risk of drug dependence is high.

**Note**
Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note**
Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-onlinepbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

- Pharmaceutical Benefits Scheme
- Reply Paid 9857
- [Your capital city]

**Restricted benefit**

Severe pain
**Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months**

**Clinical criteria:**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance, Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

**Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months**

**Clinical criteria:**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:
- (i) severe disabling pain associated with proven malignant neoplasia; or
- (ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- (iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

**Treatment Phase: Continuing PBS treatment after 1 June 2020**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:
- (i) severe disabling pain associated with malignant neoplasia; or
- (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
- (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient has received initial PBS and PBS opioid analgesic treatment as prohibited due to contraindications or intolerance.

- (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

- (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).
**MORPHINE**

Caution The risk of drug dependence is high.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

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Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

<table>
<thead>
<tr>
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<td><strong>Caution</strong> The risk of drug dependence is high.</td>
</tr>
<tr>
<td><strong>Note</strong> Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.</td>
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Reply Paid 9857

[Your capital city]
Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

**Cancer pain**

**Treatment Phase: Continuing PBS treatment after 1 June 2020**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.
- Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:
  - (i) is less than 12 months; or
  - (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
  - (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  - (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.
- Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.
- Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.
- Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

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**MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note** Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

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Pharmaceutical Benefits Scheme

Reply Paid 9857

[Your capital city]

**Restricted benefit**

**Severe pain**

**Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months**

**Clinical criteria:**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

**Severe pain**
Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance; OR
- The treatment must be part of pre-operative care; OR
- The treatment must be used as an analgesic adjunct in general anaesthesia.

Authorities for increased maximum quantities and/or repeats must only be considered for:
1. severe disabling pain associated with proven malignant neoplasia; or
2. palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
3. chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
4. chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

**Restricted benefit**

Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.
- Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:
  1. severe disabling pain associated with malignant neoplasia; or
  2. chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
  3. palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
  4. chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  5. chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

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**Morphine**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for ‘as-required’ pain relief.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-onlinePBS-authorities-hpos).

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Reply Paid 9857
[Your capital city]

Authority required
Chronic severe disabling pain
Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:
- The condition must require daily, continuous, long term opioid treatment, AND
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required
Chronic severe disabling pain
Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:
- The condition must require daily, continuous, long term opioid treatment, AND
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:
(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

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Authority required
Chronic severe disabling pain
Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:
(i) is less than 12 months; or
(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
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### morphine sulfate pentahydrate 200 mg modified release granules, 28 sachets

**Brand Name and Manufacturer:**
- **MS Contin Suspension 200 mg [MF]**

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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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### morphine sulfate pentahydrate 200 mg modified release tablet, 28

**Brand Name and Manufacturer:**
- **MS Contin [MF]**

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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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### MORPHINE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for ‘as-required’ pain relief.

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

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- [Your capital city]

**Authority required (STREAMLINED)**

**10755**

Chronic severe pain

**Clinical criteria:**
- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

**10748**

Chronic severe pain

**Clinical criteria:**
- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:
- (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; **or**
- (ii) exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; **or**
- (iii) has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.
Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

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**Authority required (STREAMLINED)**

**10752**

Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.
- Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:
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  - (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
  - (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  - (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.
- Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.
- Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.
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### morphine sulfate pentahydrate 60 mg modified release tablet, 28

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### morphine sulfate pentahydrate 10 mg modified release capsule, 28

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### morphine sulfate pentahydrate 100 mg modified release capsule, 28

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### morphine sulfate pentahydrate 120 mg modified release capsule, 14

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### morphine sulfate pentahydrate 20 mg modified release capsule, 28

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### morphine sulfate pentahydrate 50 mg modified release capsule, 28

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### morphine sulfate pentahydrate 60 mg modified release capsule, 14

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<tbody>
<tr>
<td>8492Y</td>
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### morphine sulfate pentahydrate 90 mg modified release capsule, 14

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<td>44.90</td>
<td>41.00</td>
<td>MS Mono [MF]</td>
</tr>
</tbody>
</table>
General Pharmaceutical Benefits

**MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Authority required**

Chronic severe disabling pain

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

**morphine sulfate pentahydrate 100 mg modified release granules, 28 sachets**

<table>
<thead>
<tr>
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</thead>
<tbody>
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<td>..</td>
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<td>MS Contin Suspension 100 mg</td>
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**morphine sulfate pentahydrate 20 mg modified release granules, 28 sachets**

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<td>63.33</td>
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**morphine sulfate pentahydrate 30 mg modified release granules, 28 sachets**

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**morphine sulfate pentahydrate 60 mg modified release granules, 28 sachets**

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<tr>
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**morphine sulfate pentahydrate 10 mg modified release tablet, 28**

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<tbody>
<tr>
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<td>..</td>
<td>..</td>
<td>26.31</td>
<td>27.60</td>
<td>*</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Morphine MR Mylan [AF]</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* MS Contin [MF]</td>
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**morphine sulfate pentahydrate 100 mg modified release tablet, 28**

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<td>74.44</td>
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<td>* Morphine MR AN [EA]</td>
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**morphine sulfate pentahydrate 30 mg modified release tablet, 28**

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<td></td>
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<td></td>
<td></td>
<td>* Morphine MR Mylan [AF]</td>
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**morphine sulfate pentahydrate 5 mg modified release tablet, 28**

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<tr>
<td>1</td>
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<td>24.19</td>
<td>25.48</td>
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**morphine sulfate pentahydrate 200 mg modified release granules, 28 sachets**

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**NERVOUS SYSTEM**

General Pharmaceutical Benefits 785
**NERVOUS SYSTEM**

**morphine sulfate pentahydrate 200 mg modified release tablet, 28**

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**OXYCODONE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**
- The treatment must be for short term therapy of acute severe pain, AND
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**oxycodone hydrochloride 10 mg capsule, 20**

<table>
<thead>
<tr>
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**oxycodone hydrochloride 5 mg capsule, 20**

<table>
<thead>
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**oxycodone hydrochloride 5 mg tablet, 20**

<table>
<thead>
<tr>
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<td>30.61</td>
<td>20.06</td>
<td>Endone [AF]</td>
</tr>
</tbody>
</table>

**OXYCODONE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**
- The treatment must be for post-operative pain following a major operative procedure, AND
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**oxycodone hydrochloride 10 mg capsule, 20**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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**oxycodone hydrochloride 5 mg capsule, 20**

<table>
<thead>
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**oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL**

<table>
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**oxycodone hydrochloride 5 mg tablet, 20**

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</tbody>
</table>

**OXYCODONE**

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Restricted benefit**

Severe pain

**Clinical criteria:**
- The treatment must be for post-operative pain following a major operative procedure, AND
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.
NERVOUS SYSTEM

**General Pharmaceutical Benefits**

### OXYCODONE

**Caution**
The risk of drug dependence is high.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

<table>
<thead>
<tr>
<th>Restricted benefit</th>
<th>Severe pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical criteria:</td>
<td></td>
</tr>
<tr>
<td>• The treatment must be for short term therapy of acute severe pain, <strong>AND</strong></td>
<td></td>
</tr>
<tr>
<td>• Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; <strong>OR</strong></td>
<td></td>
</tr>
<tr>
<td>• Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.</td>
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### oxycodone 30 mg suppository, 12

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<tr>
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### oxycodone hydrochloride 10 mg capsule, 20

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### oxycodone hydrochloride 5 mg capsule, 20

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### oxycodone hydrochloride 5 mg tablet, 20

<table>
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<th>Premium $</th>
<th>DPMQ $</th>
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<td>*19.93</td>
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<td>Endone [AF]</td>
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### oxycodone hydrochloride 10 mg tablet, 20

<table>
<thead>
<tr>
<th>Max. Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>*21.17</td>
<td>21.22</td>
<td>*</td>
<td>Endone [AF]</td>
</tr>
</tbody>
</table>

### OXYCODONE

**Caution**
The risk of drug dependence is high.

**Note**
Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Restricted benefit**
Severe pain

**Treatment Phase:** Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**
- Patient must have cancer pain; OR
- The treatment must be for post-operative pain following a major operative procedure, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**
Severe pain

**Treatment Phase:** Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**
- Patient must have cancer pain; OR
- The treatment must be for post-operative pain following a major operative procedure, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
NERVOUS SYSTEM

- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for:
  (i) severe disabling pain associated with proven malignant neoplasia; or
  (ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
  (iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.
Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.
Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Restricted benefit
Severe pain
Treatment Phase: Continuing PBS treatment after 1 June 2020
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.
Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:
  (i) severe disabling pain associated with malignant neoplasia; or
  (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
  (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
  (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.
Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.
Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Oxycodeone 30 mg suppository, 12

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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
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OXYCODONE

Caution

The risk of drug dependence is high.

Note

Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]
Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

**Severe pain**

**Treatment Phase: Initial PBS treatment after 1 June 2020** where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:

(i) severe disabling pain associated with proven malignant neoplasia; or
(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

**Severe pain**

**Treatment Phase: Continuing PBS treatment after 1 June 2020**

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:

(i) severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

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### oxycodone hydrochloride 10 mg capsule, 20

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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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### oxycodone hydrochloride 20 mg capsule, 20

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## NERVOUS SYSTEM

### oxycodone hydrochloride 5 mg capsule, 20

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<td>20.77</td>
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<td>* Endone [AF]</td>
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### oxycodone hydrochloride 1 mg/mL oral liquid, 250 mL

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<td>30.06</td>
<td>31.35</td>
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### oxycodone hydrochloride 5 mg tablet, 20

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<td>20.06</td>
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<td>* Oxycodone Aspen [AL] [YN]</td>
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### OXCODONE

#### Caution

The risk of drug dependence is high.

Note: This treatment is not suitable for ‘as-required’ pain relief.

Note: OxyContin and Novacodone modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

Note: Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note: Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to: Residential Benefits Scheme

Reply Paid 9857 [Your capital city]

### Authority required (STREAMLINED)

#### 10755

**Chronic severe pain**

**Treatment Phase:** Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

#### Authority required (STREAMLINED)

#### 10748

**Chronic severe pain**

**Treatment Phase:** Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).
(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

10752

Chronic severe pain
Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.
- Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:
  - (i) is less than 12 months; or
  - (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
  - (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  - (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

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**OXYCODONE**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for 'as-required' pain relief.

**Note** OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

General Pharmaceutical Benefits 791
NERVOUS SYSTEM

Authority required (STREAMLINED)

10755
Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:
- The condition must require daily, continuous, long term opioid treatment, AND
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10748
Chronic severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:
- The condition must require daily, continuous, long term opioid treatment, AND
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:
- (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
- (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10752
Chronic severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:
- (i) is less than 12 months; or
- (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
- (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

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Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).
OXYCODONE + NALOXONE

Caution
The risk of drug dependence is high.

Note
This treatment is not suitable for 'as-required' pain relief.

Note: Shared Care Model
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note
Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-onlinepbs-Authorities-hpos).

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Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required (STREAMLINED)

10755
Chronic severe pain
Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:
- The condition must require daily, continuous, long term opioid treatment, AND
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10748
Chronic severe pain
Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:
- The condition must require daily, continuous, long term opioid treatment, AND
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:
(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).
NERVOUS SYSTEM

FENTANYL

Caution
The risk of drug dependence is high.

Note
This treatment is not suitable for ‘as-required’ pain relief.

Note
Consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note
Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).
Note Pharmaceutical benefits that have the form fentanyl 12 microgram/hour patch are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
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Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

Authority required (STREAMLINED)
10745
Chronic severe disabling pain
Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:
- The condition must require daily, continuous, long term opioid treatment, AND
- Patient must not be opioid naive, AND
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.
Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.
Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)
10747
Chronic severe disabling pain
Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:
- The condition must require daily, continuous, long term opioid treatment, AND
- Patient must not be opioid naive, AND
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:
(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.
Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.
Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.
Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)
10751
Chronic severe disabling pain
Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.
Authors for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or
(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

---

### FENTANYL

**Caution**
The risk of drug dependence is high.

**Note**
This treatment is not suitable for ‘as-required’ pain relief.

**Note**
Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note**
Fentanyl transdermal patches are not recommended in opioid naïve 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).

**Note**
Pharmaceutical benefits that have the form fentanyl 25 microgram/hour patch are equivalent for the purposes of substitution.

**Note**
Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note**
Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

#### Authority required (STREAMLINED)

**10745**
Chronic severe disabling pain

**Treatment Phase:** Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**
- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

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**fentanyl 12 microgram/hour patch, 5**

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Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

### 10747

**Chronic severe disabling pain**

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**
- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:
- (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
- (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iii) has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

### 10751

**Chronic severe disabling pain**

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:
- (i) is less than 12 months; or
- (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
- (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
- (iv) has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

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**fentanyl 25 microgram/hour patch, 5 Max.Qty Packs**

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**fentanyl 25 microgram/hour patch, 5 Max.Qty Packs**

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<th>No. of Rpts</th>
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**fentanyl 25 microgram/hour patch, 5 Max.Qty Packs**

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<td>* Fentanyl Sandoz [SZ]</td>
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**NERVOUS SYSTEM**

General Pharmaceutical Benefits
### FENTANYL

**Caution** The risk of drug dependence is high.

- **Note** This treatment is not suitable for 'as-required' pain relief.
- **Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.
- **Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).
- **Note** Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to: Pharmaceutical Benefits Scheme Reply Paid 9857 [Your capital city]

**Authority required (STRAIMLINED)**

10745

Chronic severe disabling pain

**Treatment Phase:** Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STRAIMLINED)**

10747

Chronic severe disabling pain

**Treatment Phase:** Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STRAIMLINED)**

10751
Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.
- Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:
  1. is less than 12 months; or
  2. exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
  3. exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  4. has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Fentanyl

50 microgram/hour patch, 5

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<td>* Fentanyl Sandoz [SZ]</td>
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Caution The risk of drug dependence is high.

Note This treatment is not suitable for 'as-required' pain relief.

Note Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Note Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10745

Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:
- The condition must require daily, continuous, long term opioid treatment, AND
- Patient must not be opioid naive, AND
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.
Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

**10747**
Chronic severe disabling pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**
- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must not be opioid naive, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

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(ii) exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; **or**
(iii) has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

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**Authority required (STREAMLINED)**

**10751**
Chronic severe disabling pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; **or**
(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; **or**
(iii) exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; **or**
(iv) has exceeded 12 months prior to 1 June 2020 and the patient’s pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

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### fentanyl 75 microgram/hour patch, 5

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* Denpax [AF]

### fentanyl 75 microgram/hour patch, 5

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* Dutran 75 [EA]
* Fenpatch 75 [ZP]
- **FENTANYL**

  **Caution** The risk of drug dependence is high.

  **Note** This treatment is not suitable for 'as-required' pain relief.

  **Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

  **Note** Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

  **Note** Pharmaceutical benefits that have the form fentanyl 100 microgram/hour patch are equivalent for the purposes of substitution.

  **Note** Shared Care Model:

  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

  **Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/pbs/services/request-authority-using-onlinepbs-authorities-hpos).

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  Pharmaceutical Benefits Scheme
  Reply Paid 9857
  [Your capital city]

  **Authority required (STREAMLINED)**

  **10745**

  Chronic severe disabling pain

  Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

  **Clinical criteria:**

  - The condition must require daily, continuous, long term opioid treatment, **AND**
  - Patient must not be opioid naive, **AND**
  - Patient must have cancer pain; **OR**
  - Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
  - Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

  Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

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  **Authority required (STREAMLINED)**

  **10747**

  Chronic severe disabling pain

  Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

  **Clinical criteria:**

  - The condition must require daily, continuous, long term opioid treatment, **AND**
  - Patient must not be opioid naive, **AND**
  - Patient must have cancer pain; **OR**
  - Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; **OR**
  - Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

  Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

  (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

  (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

  (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

  Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.
Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

### Chronic severe disabling pain

**Treatment Phase: Continuing PBS treatment after 1 June 2020**

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:
- (i) is less than 12 months; or
- (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
- (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
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Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

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Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

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**METHADONE**

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for ‘as-required’ pain relief.

**Note** This treatment is not recommended for use in ambulant patients.

**Note** Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos). Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333. Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

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- Reply Paid 9857
- [Your capital city]

**Authority required (STREAMLINED)**

### Chronic severe disabling pain

**Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months**

**Clinical criteria:**
- The condition must require daily, continuous, long term opioid treatment, **AND**

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• Patient must not be opioid naive, AND
• Patient must have cancer pain; OR
• Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
• Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

### 10747

**Chronic severe disabling pain**

**Treatment Phase:** Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**

- The condition must require daily, continuous, long term opioid treatment, AND
- Patient must not be opioid naive, AND
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; OR
- Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:

(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(ii) exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iii) has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

### 10751

**Chronic severe disabling pain**

**Treatment Phase:** Continuing PBS treatment after 1 June 2020

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:

(i) is less than 12 months; or

(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or

(iii) exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or

(iv) has exceeded 12 months prior to 1 June 2020 and the patient’s pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

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**methadone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules**

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General Pharmaceutical Benefits
methadone hydrochloride 10 mg tablet, 20

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### BUPRENORPHINE

**Caution** The risk of drug dependence is high.

**Note** This treatment is not suitable for ‘as-required’ pain relief.

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Real-time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-onlinepbs-authorities-hpos).

Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required (STREAMLINED) 10755**
Chronic severe pain
Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**
- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED) 10748**
Chronic severe pain
Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**
- The condition must require daily, continuous, long term opioid treatment, **AND**
- Patient must have cancer pain; **OR**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; **OR**
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:
(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
(ii) exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(iii) has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

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Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED) 10752**
Chronic severe pain
Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:
  (i) is less than 12 months; or
  (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
  (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.
Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

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Opioids in combination with non-opioid analgesics

- PARACETAMOL + CODEINE
  Caution The risk of drug dependence is high.
  Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit
Severe pain
Clinical criteria:
- The treatment must be for short term therapy of acute severe pain, **AND**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

<p>| paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20 |</p>
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**Paracetamol + Codeine**

- **Clinical criteria:**
  - Severe pain
  - Severe pain treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

- **Restricted benefit:**
  - Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics
  - Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics
  - Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics

- **Caution:**
  - The risk of drug dependence is high.

- **Note:**
  - No increase in the maximum number of repeats may be authorised.

---

**PARACETAMOL + CODEINE**

- **Caution:**
  - The risk of drug dependence is high.

- **Note:**
  - No increase in the maximum number of repeats may be authorised.

---

**PARACETAMOL + CODEINE**

- **Caution:**
  - The risk of drug dependence is high.

- **Note:**
  - No increase in the maximum number of repeats may be authorised.

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**PARACETAMOL + CODEINE**

- **Caution:**
  - The risk of drug dependence is high.

- **Note:**
  - No increase in the maximum number of repeats may be authorised.

---

**PARACETAMOL + CODEINE**

- **Caution:**
  - The risk of drug dependence is high.

- **Note:**
  - No increase in the maximum number of repeats may be authorised.

---

**PARACETAMOL + CODEINE**

- **Caution:**
  - The risk of drug dependence is high.

- **Note:**
  - No increase in the maximum number of repeats may be authorised.

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**PARACETAMOL + CODEINE**

- **Caution:**
  - The risk of drug dependence is high.

- **Note:**
  - No increase in the maximum number of repeats may be authorised.

---

**PARACETAMOL + CODEINE**

- **Caution:**
  - The risk of drug dependence is high.

- **Note:**
  - No increase in the maximum number of repeats may be authorised.

---

**PARACETAMOL + CODEINE**

- **Caution:**
  - The risk of drug dependence is high.

- **Note:**
  - No increase in the maximum number of repeats may be authorised.
Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**
Severe pain

Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

**Clinical criteria:**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for:
(i) severe disabling pain associated with proven malignant neoplasia; or
(ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is incapable of having annual pain management review due to their clinical condition; or
(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

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**Restricted benefit**
Severe pain

Treatment Phase: Continuing PBS treatment after 1 June 2020

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:
(i) severe disabling pain associated with malignant neoplasia; or
(ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
(iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

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### paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet, 20

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<td>* Panadeine Forte [SW]</td>
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</table>

**Other opioids**

- **TAPENTADOL**

  **Caution** The risk of drug dependence is high.

  **Note** This treatment is not suitable for ‘as-required’ pain relief.
**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note:** Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-onlinepbs-authorities-hpos).
Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
Pharmaceutical Benefits Scheme
Reply Paid 9857
[Your capital city]

**Authority required (STREAMLINED)**

**10755**
Chronic severe pain
Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months
Clinical criteria:
- The condition must require daily, continuous, long term opioid treatment, AND
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.
Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.
Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

**10748**
Chronic severe pain
Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months
Clinical criteria:
- The condition must require daily, continuous, long term opioid treatment, AND
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.
Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:
(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.
Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.
Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.
Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Authority required (STREAMLINED)**

**10752**
Chronic severe pain
Treatment Phase: Continuing PBS treatment after 1 June 2020
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.
Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:
(i) is less than 12 months; or
(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

dapoxetine 100 mg modified release tablet, 28

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dapoxetine 250 mg modified release tablet, 28

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### TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

#### Restricted benefit

Severe pain

**Clinical criteria:**
- The treatment must be for short term therapy of acute severe pain, AND
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**tramadol hydrochloride 50 mg capsule, 20**

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\(^1\)1.50 "16.66 16.45 " Tramal [CS]

### TRAMADOL

**Caution** The risk of drug dependence is high.

**Note** Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

#### Restricted benefit

Severe pain

**Clinical criteria:**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**tramadol hydrochloride 50 mg capsule, 20**

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\(^2\)2.42 16.44 15.31 " Tramal [CS]
### NERVOUS SYSTEM

**tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules**

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**tramadol hydrochloride 100 mg/mL oral liquid, 10 mL**

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**TRAMADOL**

Caution: The risk of drug dependence is high.

**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.

**Restricted benefit**

Severe pain

**Clinical criteria:**
- The treatment must be for short term therapy of acute severe pain, AND
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**tramadol hydrochloride 50 mg capsule, 20**

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<td>Zydol [PW]</td>
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**TRAMADOL**

Caution: The risk of drug dependence is high.

**Note**
- Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos).
- Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
- Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to: Pharmaceutical Benefits Scheme
  Reply Paid 9857
  [Your capital city]

**Restricted benefit**

Severe pain

**Treatment Phase:** Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

**Clinical criteria:**
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics; OR
- Patient must be unable to use non-opioid analgesics due to contraindications or intolerance.

**Authorities for increased maximum quantities and/or repeats must only be considered for:**
- Severe disabling pain associated with malignant neoplasia; or
- Palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
- Palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or

### Schedule of Pharmaceutical Benefits – December 2020
(iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

**Restricted benefit**

Severe pain

**Treatment Phase:** Continuing PBS treatment after 1 June 2020

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.
- Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:
  - (i) severe disabling pain associated with malignant neoplasia; or
  - (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or
  - (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or
  - (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient’s clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
  - (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient’s clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

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### tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules

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### tramadol hydrochloride 100 mg/mL oral liquid, 10 mL

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**TRAMADOL**

**Caution**

The risk of drug dependence is high.

**Note**

This treatment is not suitable for ‘as-required’ pain relief.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note**

Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos). Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.

Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:

Pharmaceutical Benefits Scheme
Authority required (STREAMLINED)

10755
Chronic severe pain
Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months

Clinical criteria:
- The condition must require daily, continuous, long term opioid treatment, AND
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.

Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.

Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Authority required (STREAMLINED)

10748
Chronic severe pain
Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

Clinical criteria:
- The condition must require daily, continuous, long term opioid treatment, AND
- Patient must have cancer pain; OR
- Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics; OR
- Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:
(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
(ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

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Authority required (STREAMLINED)

10752
Chronic severe pain
Treatment Phase: Continuing PBS treatment after 1 June 2020

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:
(i) is less than 12 months; or
(ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or
(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or
(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.

Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.

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### Tramadol Hydrochloride 100 mg Modified Release Tablet, 20

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</tr>
<tr>
<td></td>
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<td></td>
<td>Tramadol SR generichealth [GQ]</td>
</tr>
<tr>
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<td></td>
<td>Tramado SR [AL]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.49</td>
<td>18.92</td>
<td>15.72</td>
<td>Tramal SR 100 [CS]</td>
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### Tramadol Hydrochloride 150 mg Modified Release 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>1</td>
<td>15.25</td>
<td>16.54</td>
<td></td>
<td>APO-Tramadol SR [TX]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>Tramadol AN SR [EA]</td>
</tr>
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<td></td>
<td>Tramadol Sandoz SR [SZ]</td>
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<td>Tramadol SR generichealth [GQ]</td>
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<td></td>
<td></td>
<td>Tramado SR [AL]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.37</td>
<td>20.62</td>
<td>16.54</td>
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### Tramadol Hydrochloride 200 mg Modified Release Tablet, 20

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<tr>
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<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>15.96</td>
<td>17.25</td>
<td></td>
<td>APO-Tramadol SR [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tramadol AN SR [EA]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tramadol Sandoz SR [SZ]</td>
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<td>Tramadol SR generichealth [GQ]</td>
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<td>Tramado SR [AL]</td>
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<td>22.04</td>
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### Tramadol Hydrochloride 50 mg Modified Release Tablet, 20

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<tbody>
<tr>
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<td>15.17</td>
<td>16.46</td>
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<td>Tramal SR 50 [CS]</td>
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### Other Analgesics and Antipyretics

#### Analides

**Paracetamol**

**Restricted Benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander.

### Paracetamol 120/5 mL Oral Liquid, 100 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
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<td>14.59</td>
<td>15.88</td>
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<td>Panamax [SW]</td>
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### Paracetamol 240/5 mL Oral Liquid, 200 mL

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<tr>
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<td>Panamax 240 Elixir [SW]</td>
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### Paracetamol 500 mg Tablet, 100

<table>
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<td></td>
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<td>Mendeleev Paracetamol [HX]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Paracetamol (Sandoz) [SZ]</td>
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<td></td>
<td>Parapane [AF]</td>
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<td></td>
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<td>Febridol [EA]</td>
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<td></td>
<td>Paralgin [OW]</td>
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<td></td>
<td>PHARMACY CARE</td>
</tr>
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<td></td>
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<td></td>
<td></td>
<td>PARACETAMOL [SI]</td>
</tr>
</tbody>
</table>

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**General Pharmaceutical Benefits**
**NERVOUS SYSTEM**

### PARacetamol

**Restricted benefit**

Chronic arthropathies

**Population criteria:**
- Patient must identify as Aboriginal or Torres Strait Islander.

<table>
<thead>
<tr>
<th>Paracetamol 500 mg tablet, 100</th>
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</thead>
<tbody>
<tr>
<td>5224Y</td>
</tr>
<tr>
<td>Max.Qty Packs</td>
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<tr>
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</table>

### PARacetamol

**Restricted benefit**

Chronic arthropathies

**Population criteria:**
- Patient must identify as Aboriginal or Torres Strait Islander.

<table>
<thead>
<tr>
<th>Paracetamol 500 mg tablet, 100</th>
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</thead>
<tbody>
<tr>
<td>8784H</td>
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<tr>
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<tr>
<td></td>
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<tr>
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</tr>
</tbody>
</table>

### PARacetamol

**Note** Pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 96 and pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 192 are equivalent for the purposes of substitution.

**Restricted benefit**

Persistent pain

**Clinical criteria:**
- The condition must be associated with osteoarthritis.

**Population criteria:**
- Patient must identify as Aboriginal or Torres Strait Islander.

<table>
<thead>
<tr>
<th>Paracetamol 665 mg modified release tablet, 96</th>
</tr>
</thead>
<tbody>
<tr>
<td>8814X</td>
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<tr>
<td>Max.Qty Packs</td>
</tr>
<tr>
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</tbody>
</table>

### Other Analgesics and Antipyretics

**Pregabalin**

**Note** Continuing Therapy Only:
- For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED) 4172**

Neuropathic pain

**Clinical criteria:**
- The condition must be refractory to treatment with other drugs.

<table>
<thead>
<tr>
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</thead>
<tbody>
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</table>
pregabalin 25 mg capsule, 56
2348N

<table>
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<th>Pack</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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Brand Name and Manufacturer:
- BTC PREGABALIN [JB]
- LYPRALIN [RW]
- Lyzalon [AF]
- Pregabalin AMNEAL [EA]
- PREGABALIN-DRLA [RZ]
- Pregabalin Sandoz [SZ]
- Cipla Pregabalin [LR]
- Lyrica [UJ]
- Neuroccord [CR]
- Pregabalin APOTEX [GX]
- Pregabalin GH [GQ]
- Pregabalin-Teva [TB]

pregabalin 300 mg capsule, 56
2363J

<table>
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<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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Brand Name and Manufacturer:
- BTC PREGABALIN [JB]
- LYPRALIN [RW]
- Lyzalon [AF]
- Pregabalin AMNEAL [EA]
- PREGABALIN-DRLA [RZ]
- Pregabalin Sandoz [SZ]
- Cipla Pregabalin [LR]
- Lyrica [UJ]
- Neuroccord [CR]
- Pregabalin APOTEX [GX]
- Pregabalin GH [GQ]
- Pregabalin-Teva [TB]

pregabalin 75 mg capsule, 56
2335X

<table>
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<th>Pack</th>
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Brand Name and Manufacturer:
- BTC PREGABALIN [JB]
- LYPRALIN [RW]
- Lyzalon [AF]
- Pregabalin AMNEAL [EA]
- PREGABALIN-DRLA [RZ]
- Pregabalin Sandoz [SZ]
- Cipla Pregabalin [LR]
- Lyrica [UJ]
- Neuroccord [CR]
- Pregabalin APOTEX [GX]
- Pregabalin GH [GQ]
- Pregabalin-Teva [TB]

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.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Migraine attack

Clinical criteria:
- The condition must have usually failed to respond to analgesics in the past.

**Eletriptan 40 mg tablet, 4**
5290K

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
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<td>27.17</td>
<td>28.46</td>
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</tbody>
</table>

Brand Name and Manufacturer: Relpax [UJ]

**Eletriptan 80 mg tablet, 4**
5291L

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<th>Pack</th>
<th>No. of Rpts</th>
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<td>1</td>
<td>5</td>
<td>..</td>
<td>27.17</td>
<td>28.46</td>
<td></td>
</tr>
</tbody>
</table>

Brand Name and Manufacturer: Relpax [UJ]

**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.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required
Migraine attack

Clinical criteria:
- The condition must have usually failed to respond to analgesics in the past.

**Naratriptan 2.5 mg tablet, 2**
8298R

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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Brand Name and Manufacturer: Naramig [AS]
**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.

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

*Note* Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Migraine attack

**Clinical criteria:**
- The condition must have usually failed to respond to analgesics in the past, AND
- Patient must be one in whom adverse events have occurred with other suitable PBS-listed drugs.

**naratriptan 2.5 mg tablet, 29734H**

<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>29.03</td>
<td>Naramig [AS]</td>
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**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.

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

*Note* Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Migraine attack

**Clinical criteria:**
- The condition must have usually failed to respond to analgesics in the past, AND
- Patient must be one in whom drug interactions are expected to occur with other suitable PBS-listed drugs.

**Rizatriptan 10 mg orally disintegrating tablet, 2 10551H**

<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><em>Rizatriptan ODT APOTEX [GX]</em></td>
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<td>RIXALT [RF]</td>
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**Rizatriptan 10 mg wafer, 2 9313E**

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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>2</td>
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<td>20.82</td>
<td>22.11</td>
<td>Maxalt [AL]</td>
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<td></td>
<td></td>
<td></td>
<td>*Rizatriptan Wifers-10mg [AF]</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.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Migraine attack

Clinical criteria:
- The condition must have usually failed to respond to analgesics in the past.

SUMATRIPTAN Tablet 50 mg (base) (fast disintegrating), 4

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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sumatriptan 50 mg tablet, 4

<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>
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</thead>
</table>

sumatriptan 20 mg/actuation nasal spray, 2 x 1 actuation

<table>
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<th>No. of Rpts</th>
<th>Premium $</th>
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sumatriptan 50 mg tablet, 2

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<tr>
<td>8144P</td>
<td>5</td>
<td>$4.20</td>
<td>21.38</td>
<td>18.47</td>
<td>Imigran [LN]</td>
</tr>
</tbody>
</table>

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>5</td>
<td>$4.20</td>
<td>21.38</td>
<td>18.47</td>
<td>Imigran FDT [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.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Migraine attack

Clinical criteria:
- The condition must have usually failed to respond to analgesics in the past.

zolmitriptan 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>8266C</td>
<td>5</td>
<td>$2.76</td>
<td>26.66</td>
<td>25.19</td>
<td>Zomig [AP]</td>
</tr>
</tbody>
</table>

Other antimigraine preparations

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.
### NERVOUS SYSTEM

#### pizotifen 500 microgram 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></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sandomigran 0.5 [AE]</td>
</tr>
</tbody>
</table>

#### ANTIEPILEPTICS

**Barbiturates and derivatives**

#### PHENOBARBITAL (PHENOBARBITONE)

**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>phenobarbital (phenobarbitone) sodium 219 mg/mL injection, 5 x 1 mL ampoules</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>Fawns and McAllan Proprietary Limited [AS]</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>primidone 250 mg tablet, 200</th>
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<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></td>
<td>Mysoline [LM]</td>
</tr>
</tbody>
</table>

#### PHENYTOIN

**Note Continuing Therapy Only:**
- For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
<thead>
<tr>
<th>phenytoin 30 mg/5 mL oral liquid, 500 mL</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></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Dilantin [UJ]</td>
</tr>
</tbody>
</table>

#### ETHOSUXIMIDE

**Note Continuing Therapy Only:**
- For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
NERVOUS SYSTEM

ethosuximide 250 mg/5 mL oral liquid, 200 mL

<table>
<thead>
<tr>
<th>1414K</th>
<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></td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>72.61</td>
<td>41.00</td>
<td>Zarontin [IX]</td>
</tr>
</tbody>
</table>

**ETHOSUXIMIDE**

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the form ethosuximide 250 mg capsule, 200 and pharmaceutical benefits that have the form ethosuximide 250 mg capsule, 100 are equivalent for the purposes of substitution.

ethosuximide 250 mg capsule, 200

<table>
<thead>
<tr>
<th>1413J</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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>294.88</td>
<td>41.00</td>
<td>* Zarontin [IX]</td>
</tr>
</tbody>
</table>

**Benzodiazepine derivatives**

**CLONAZEPAM**

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.

**Restricted benefit**

Epilepsy

clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (&) inert substance diluent [5 x 1 mL ampoules], 1 pack

<table>
<thead>
<tr>
<th>1807D</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>22.59</td>
<td>23.88</td>
<td>Rivotril [RO]</td>
</tr>
</tbody>
</table>

**CLONAZEPAM**

Caution Abuse of clonazepam has been reported. Refer to the current product information.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Epilepsy

Clinical criteria:
- The condition must be neurologically proven.

clonazepam 2.5 mg/mL (0.1 mg/drop) oral liquid, 10 mL

<table>
<thead>
<tr>
<th>1808E</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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</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*19.52</td>
<td>20.81</td>
<td>Rivotril [RO]</td>
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</tbody>
</table>

clonazepam 2 mg tablet, 100

<table>
<thead>
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<th>1806C</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>2</td>
<td>..</td>
<td>*33.44</td>
<td>34.73</td>
<td>Paxam 2 [AF]</td>
</tr>
</tbody>
</table>

**CLONAZEPAM**

Caution Abuse of clonazepam has been reported. Refer to the current product information.

Note Pharmaceutical benefits that have form pack size clonazepam 500 microgram tablet, 100 and clonazepam 500 microgram tablet, 50 are equivalent for the purposes of substitution.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Epilepsy

Clinical criteria:
- The condition must be neurologically proven.

clonazepam 500 microgram tablet, 100

<table>
<thead>
<tr>
<th>1805B</th>
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<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>2</td>
<td>..</td>
<td>*23.42</td>
<td>24.71</td>
<td>* Paxam 0.5 [AF]</td>
</tr>
</tbody>
</table>
**NERVOS SYSTEM**

### NITRAZEPAM

**Note**: Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

- Myoclonic epilepsy
- Malignant neoplasia (late stage)

**Authority required**

- Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

- Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

---

### clonazepam 500 microgram tablet, 50

<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>11559J</td>
<td>4</td>
<td>3.68</td>
<td>27.10</td>
<td>24.71</td>
<td>Rivotril [RO]</td>
</tr>
</tbody>
</table>

---

### NITRAZEPAM

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

- Myoclonic epilepsy
- Malignant neoplasia (late stage)

**Authority required**

- Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

- Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

---

### nitrazepam 5 mg tablet, 25

<table>
<thead>
<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>2732T</td>
<td>2</td>
<td>..</td>
<td>15.24</td>
<td>16.53</td>
<td>Mogadon [IL]</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.

**Authority required**

- Myoclonic epilepsy

**Authority required**

- Malignant neoplasia (late stage)

**Authority required**

- Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

---

### carbamazepine 100 mg/5 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>5041H</td>
<td>3</td>
<td>25.00</td>
<td>26.29</td>
<td></td>
<td>Tegretol Liquid [NV]</td>
</tr>
</tbody>
</table>

---

### carbamazepine 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>5039F</td>
<td>2</td>
<td>..</td>
<td>23.78</td>
<td>25.07</td>
<td>* Carbamazepine Sandoz [SZ]</td>
</tr>
</tbody>
</table>

---

### carbamazepine 200 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>1724R</td>
<td>2</td>
<td>..</td>
<td>31.66</td>
<td>32.95</td>
<td>* Carbamazepine Sandoz [SZ]</td>
</tr>
</tbody>
</table>

---

### carbamazepine 200 mg modified release tablet, 200

<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>5038E</td>
<td>1</td>
<td>..</td>
<td>32.07</td>
<td>33.36</td>
<td>Tegretol CR 200 [NV]</td>
</tr>
</tbody>
</table>

---

### carbamazepine 400 mg modified release tablet, 200

<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>5037D</td>
<td>1</td>
<td>..</td>
<td>50.13</td>
<td>41.00</td>
<td>Tegretol CR 400 [NV]</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.

**Authority required**

- Myoclonic epilepsy

**Authority required**

- Malignant neoplasia (late stage)

**Authority required**

- Insomnia

**Clinical criteria:**

- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

---

### carbamazepine 100 mg/5 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>2427R</td>
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<td>26.29</td>
<td></td>
<td>Tegretol Liquid [NV]</td>
</tr>
</tbody>
</table>
## NERVOUS SYSTEM

### General Pharmaceutical Benefits

#### Carbamazepine 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>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>2</td>
<td>..</td>
<td>•23.78</td>
<td>25.07</td>
<td>Carbamazepine Sandoz [SZ]</td>
</tr>
</tbody>
</table>

#### Carbamazepine 200 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>2</td>
<td>2</td>
<td>..</td>
<td>•31.66</td>
<td>32.95</td>
<td>Carbamazepine Sandoz [SZ]</td>
</tr>
</tbody>
</table>

#### Carbamazepine 200 mg modified release tablet, 200

<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>32.07</td>
<td>33.36</td>
<td>Tegretol CR 200 [NV]</td>
</tr>
</tbody>
</table>

#### Carbamazepine 400 mg modified release tablet, 200

<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>50.13</td>
<td>41.00</td>
<td>Tegretol CR 400 [NV]</td>
</tr>
</tbody>
</table>

### Oxcarbazepine

**Note** Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

5183

**Seizures**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

#### Oxcarbazepine 60 mg/mL oral liquid, 250 mL

<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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</thead>
<tbody>
<tr>
<td>2</td>
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<td>..</td>
<td>*109.26</td>
<td>41.00</td>
<td>Trileptal [NV]</td>
</tr>
</tbody>
</table>

#### Oxcarbazepine 150 mg tablet, 100

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
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<td>5</td>
<td>..</td>
<td>92.25</td>
<td>41.00</td>
<td>Trileptal [NV]</td>
</tr>
</tbody>
</table>

#### Oxcarbazepine 300 mg tablet, 100

<table>
<thead>
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<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>5</td>
<td>..</td>
<td>147.78</td>
<td>41.00</td>
<td>Trileptal [NV]</td>
</tr>
</tbody>
</table>

**Fatty acid derivatives**

### Tiagabine

**Note** Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

4928

**Partial epileptic seizures**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

#### Tiagabine 10 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>2</td>
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<td>*109.80</td>
<td>41.00</td>
<td>Gabitril [TB]</td>
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#### Tiagabine 15 mg tablet, 50

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**NERVOUS SYSTEM**

**tiagabine 5 mg tablet, 50**

<table>
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<th>Brand Name and Manufacturer</th>
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</thead>
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<td>..</td>
<td>60.90</td>
<td>41.00</td>
<td>Gabitril [TB]</td>
</tr>
</tbody>
</table>

**VALPROATE**

**Caution**

There are reports of fatal hepatotoxicity, particularly in children. There is increasing evidence of dose-related teratogenesis from this drug.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**valproate sodium 200 mg/5 mL oral liquid, 300 mL**

<table>
<thead>
<tr>
<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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</thead>
<tbody>
<tr>
<td>2</td>
<td>2</td>
<td>..</td>
<td>39.98</td>
<td>41.00</td>
<td>Epilim Liquid [SW]</td>
</tr>
</tbody>
</table>

**valproate sodium 200 mg/5 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>
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<tr>
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**valproate sodium 100 mg tablet, 100**

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<th>MRVSN $</th>
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</tr>
</thead>
<tbody>
<tr>
<td>2</td>
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<td>34.26</td>
<td>35.55</td>
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**valproate sodium 200 mg enteric tablet, 100**

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*2.00 | *25.76 | 25.05 | * Epilim EC [SW] |

**valproate sodium 500 mg enteric tablet, 100**

<table>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>2</td>
<td>2</td>
<td>..</td>
<td>35.26</td>
<td>36.55</td>
<td>* Sodium Valproate Sandoz [SZ]</td>
</tr>
</tbody>
</table>

*2.00 | *37.26 | 36.55 | * Epilim EC [SW] |

**VIGABATRIN**

**Caution**

Visual field defects have been reported with this drug.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4929**

Epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**vigabatrin 500 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>94.98</td>
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**vigabatrin 500 mg powder for oral liquid, 60 sachets**

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**Other antiepileptics**

**BRIVARACETAM**

**Authority required (STREAMLINED)**

**10210**

Intractable partial epileptic seizures

**Treatment criteria:**

- Must be treated by a neurologist.

**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 not be given concomitantly with levetiracetam, except for cross titration.

### brivaracetam 100 mg tablet, 56

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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</thead>
<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>163.69</td>
<td>41.00</td>
<td>Briviact [UC]</td>
</tr>
</tbody>
</table>

### BRIVARACETAM

**Authority required (STREAMLINED)**

**10251**

Intractable partial epileptic seizures

**Treatment Phase: Initial treatment**

**Treatment criteria:**
• Must be treated by a neurologist.

**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**
• Patient must be unable to take a solid dose form of this drug, **AND**
• The treatment must not be given concomitantly with levetiracetam, except for cross titration.

### brivaracetam 10 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>
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</thead>
<tbody>
<tr>
<td>1</td>
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<td>202.85</td>
<td>41.00</td>
<td>Briviact [UC]</td>
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</tbody>
</table>

### BRIVARACETAM

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**10208**

Intractable partial epileptic seizures

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
• Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
• The treatment must not be given concomitantly with levetiracetam.

### brivaracetam 100 mg tablet, 56

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<tbody>
<tr>
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### brivaracetam 25 mg tablet, 56

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<tr>
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<td>Briviact [UC]</td>
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### brivaracetam 50 mg tablet, 56

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### brivaracetam 75 mg tablet, 56

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<td>..</td>
<td>163.69</td>
<td>41.00</td>
<td>Briviact [UC]</td>
</tr>
</tbody>
</table>
### BRIVARACETAM

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**10330**
Intractable partial epileptic seizures
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously been treated with PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be unable to take a solid dose form of this drug, **AND**
- The treatment must not be given concomitantly with levetiracetam.

**brivaracetam 10 mg/mL oral liquid, 300 mL**

<table>
<thead>
<tr>
<th>Max Qty</th>
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<th>DPMQ</th>
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</thead>
<tbody>
<tr>
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<td></td>
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<td>41.00</td>
<td>Briviact [UC]</td>
</tr>
</tbody>
</table>

### GABAPENTIN

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**4928**
Partial epileptic seizures

**Clinical criteria:**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**gabapentin 800 mg tablet, 100**

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<td>50.99</td>
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**gabapentin 100 mg capsule, 100**

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<th>DPMQ</th>
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**gabapentin 300 mg capsule, 100**

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<td>25.52</td>
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**gabapentin 400 mg capsule, 100**

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**gabapentin 600 mg tablet, 100**

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<td>41.00</td>
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</table>

### LACOSAMIDE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a
patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**8813**  
Intractable partial epileptic seizures  
Treatment Phase: Initial treatment  
**Treatment criteria:**  
- Must be treated by a neurologist.

**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.

### LACOSAMIDE

**Note Continuing Therapy Only:**  
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**8815**  
Intractable partial epileptic seizures  
Treatment Phase: Continuing treatment  
**Clinical criteria:**  
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

### LACOSAMIDE

**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

Note: Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
8770
Intractable partial epileptic seizures
Treatment Phase: Initial treatment
Treatment criteria:
- Must be treated by a neurologist.
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.

Authority required (STREAMLINED)
8815
Intractable partial epileptic seizures
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

LAMOTRIGINE

Note: Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
5138
Epileptic seizures
Clinical criteria:
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

lamotrigine 100 mg tablet, 56

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
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<td>APO-Lamotrigine [TX]</td>
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<td>Lamotrigine GH [GQ]</td>
</tr>
<tr>
<td>Logem [AL]</td>
</tr>
<tr>
<td>Sandoz Lamotrigine [HX]</td>
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<tr>
<td>LAMITAN [RF]</td>
</tr>
<tr>
<td>Lamotrigine Aspen 100 [RW]</td>
</tr>
<tr>
<td>Lamotrigine Sandoz [SZ]</td>
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<td>Reedos 100 [DO]</td>
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lamotrigine 200 mg tablet, 56

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<tr>
<td>Lamotrigine Sandoz [SZ]</td>
</tr>
<tr>
<td>Reedos 200 [DO]</td>
</tr>
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</table>

lamotrigine 10 mg/mL oral liquid, 200 mL

<table>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>LAMOTRIGINE</td>
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<tr>
<td>APO-Lamotrigine [TX]</td>
</tr>
<tr>
<td>Lamotrigine AN [EA]</td>
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<td>Lamotrigine GH [GQ]</td>
</tr>
<tr>
<td>Logem [AL]</td>
</tr>
<tr>
<td>Sandoz Lamotrigine [HX]</td>
</tr>
<tr>
<td>LAMITAN [RF]</td>
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<tr>
<td>Lamotrigine Aspen 100 [RW]</td>
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<tr>
<td>Lamotrigine Sandoz [SZ]</td>
</tr>
<tr>
<td>Reedos 100 [DO]</td>
</tr>
</tbody>
</table>
### 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.

**Authority required (STREAMLINED)**

_7603_

Partial epileptic seizures

**Clinical criteria:**

- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

#### levetiracetam 1 g tablet, 60

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<th>DPMO $</th>
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<th>Brand Name and Manufacturer</th>
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<td>41.00</td>
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<td>* Keppra [UC]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Kerron 1000 [DO]</td>
<td>* Kevtam 1000 [AF]</td>
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<td>* Levecetam 1000 [RZ]</td>
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#### levetiracetam 250 mg tablet, 60

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<td>* Kevtam 250 [AF]</td>
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<td>* Levecetam 250 [RZ]</td>
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<td>* Levetiracetam GH [GQ]</td>
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#### levetiracetam 500 mg tablet, 60

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<td>* Kevtam 500 [AF]</td>
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### 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.

**Authority required (STREAMLINED)**

_7620_

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General Pharmaceutical Benefits 827
Partial epileptic seizures

Clinical criteria:
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- Patient must be unable to take a solid dose form of levetiracetam, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

### Levetiracetam 100 mg/mL oral liquid, 300 mL

<table>
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<td>* Kerron [DO]</td>
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### 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, **AND**
- The treatment must not be given concomitantly with brivaracetam, except for cross titration.

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>
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### Perampanel

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

4658

Intractable partial epileptic seizures

Treatment Phase: Continuing

Clinical criteria:
- Patient must have previously been issued with an authority prescription for this drug.

### Perampanel 6 mg tablet, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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### Perampanel 10 mg tablet, 28

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### Perampanel 12 mg tablet, 28

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### Perampanel 4 mg tablet, 28

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### Perampanel

**Note** No applications for increased maximum quantities will be authorised.

### Authority required (STREAMLINED)

7815

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Initial treatment

Treatment criteria:
- Must be treated by a neurologist.
Clinical criteria:
- The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs, AND
- The treatment must be in combination with at least one PBS-subsidised anti-epileptic drug, AND
- The treatment must be for dose titration purposes.

Population criteria:
- Patient must be aged 12 years or older.

perampanel 2 mg tablet, 7

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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PERAMPELAN

Note No applications for increased maximum quantities will be authorised.
Note Special Pricing Arrangements apply.
Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

7789
Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Population criteria:
- Patient must be aged 12 years or older.

perampanel 6 mg tablet, 28

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<th>Premium $</th>
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STIRIPENTOL

Authority required (STREAMLINED)

10632
Severe myoclonic epilepsy in infancy (Dravet syndrome)

Clinical criteria:
- Patient must have, or have had, generalised tonic-clonic seizures or generalised clonic seizures that are not adequately controlled with a benzodiazepine and valproate, AND
- The treatment must be as adjunctive therapy to a benzodiazepine and valproate.

Treatment criteria:
- Must be treated by a neurologist if treatment is being initiated; OR
- Must be treated by a neurologist if treatment is being continued or re-initiated; OR
- Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; OR
- Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.

stiripentol 250 mg capsule, 60

<table>
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<tr>
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stiripentol 250 mg powder for oral liquid, 60 sachets

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## NERVOUS SYSTEM

### stiriipentol 500 mg capsule, 60

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### stiriipentol 500 mg powder for oral liquid, 60 sachets

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### 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 50 mg tablet, 200

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### sulthiame 200 mg tablet, 200

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### 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.

**Authority required (STREAMLINED)**

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**Seizures**

**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

### topiramate 100 mg tablet, 60

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<td></td>
<td>* Topamax [JC]</td>
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<td></td>
<td>* Topiramate Sandoz [SZ]</td>
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### topiramate 200 mg tablet, 60

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### 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.

**Authority required (STREAMLINED)**

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**Seizures**

**Clinical criteria:**

- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures; OR
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**
- Patient must be unable to take a solid dose form of topiramate.

### topiramate 15 mg capsule, 60

<table>
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</table>
### 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.

#### Authority required (STREAMLINED)

**5516**
Seizures

**Clinical criteria:**
- Patient must have partial epileptic seizures; **OR**
- Patient must have primary generalised tonic-clonic seizures; **OR**
- Patient must have seizures of the Lennox-Gastaut syndrome, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

**Authority required (STREAMLINED)**

**5325**
Migraine

**Clinical criteria:**
- The treatment must be for prophylaxis, **AND**
- Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months, **AND**
- Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; **OR**
- Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker, **AND**
- Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; **OR**
- Patient must have 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.

### ZONISAMIDE

**Note** Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

**4928**
Partial epileptic seizures

**Clinical criteria:**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

### General Pharmaceutical Benefits

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Topiramate 25 mg capsule, 60</strong></td>
<td><strong>Topiramate 25 mg capsule, 60</strong></td>
</tr>
<tr>
<td><strong>Max Qty Packs</strong></td>
<td><strong>No. of Rpts</strong></td>
</tr>
<tr>
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<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td><strong>Topiramate 50 mg capsule, 60</strong></td>
<td><strong>Topiramate 50 mg capsule, 60</strong></td>
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### Zonisamide 25 mg capsule, 56

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<td><strong>Zonisamide 25 mg capsule, 56</strong></td>
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</tr>
<tr>
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</table>
### Anti-Parkinson Drugs

#### Anticholinergic Agents

**Tertiary amines**

<table>
<thead>
<tr>
<th>Drug 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>
</thead>
<tbody>
<tr>
<td>Trihexyphenidyl (benzhexol) hydrochloride 2 mg tablet, 200</td>
<td>1</td>
<td>2</td>
<td>18.65</td>
<td>19.94</td>
<td></td>
<td>Artane [RW]</td>
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<tr>
<td>Trihexyphenidyl (benzhexol) hydrochloride 5 mg tablet, 200</td>
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<td>1</td>
<td>23.48</td>
<td>24.77</td>
<td></td>
<td>Artane [RW]</td>
</tr>
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</table>

**Ethers of tropine or tropine derivatives**

<table>
<thead>
<tr>
<th>Drug 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>Benztropine mesilate 2 mg tablet, 60</td>
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<td>18.17</td>
<td>19.46</td>
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<tr>
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#### Dopaminergic 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.*

<table>
<thead>
<tr>
<th>Drug Description</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
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<td>36.27</td>
<td></td>
<td>Madopar 125 [RO]</td>
</tr>
<tr>
<td>Levodopa 100 mg + benzerazide 25 mg modified release capsule, 100</td>
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<td>38.56</td>
<td></td>
<td>Madopar HBS [RO]</td>
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<tr>
<td>Levodopa 200 mg + benzerazide 50 mg capsule, 100</td>
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<td>5</td>
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<td>41.00</td>
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<tr>
<td>Levodopa 50 mg + benzerazide 12.5 mg capsule, 100</td>
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<td>23.73</td>
<td>25.02</td>
<td></td>
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<tr>
<td>Levodopa 100 mg + benzerazide 25 mg dispersible tablet, 100</td>
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<td>5</td>
<td>34.98</td>
<td>36.27</td>
<td></td>
<td>Madopar Rapid 125 [RO]</td>
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</table>
### levdopa 50 mg + benserazide 12.5 mg dispersible tablet, 100

<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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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>23.73</td>
<td>25.02</td>
<td>Madopar Rapid 62.5 [RO]</td>
</tr>
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</table>

### levdopa 100 mg + benserazide 25 mg tablet, 100

<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>34.98</td>
<td>36.27</td>
<td>Madopar 125 [RO]</td>
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### levdopa 200 mg + benserazide 50 mg tablet, 100

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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>43.77</td>
<td>41.00</td>
<td>Madopar [RO]</td>
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</tbody>
</table>

### LEVODOPA + CARBIDOPA

**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.

### levdopa 100 mg + carbidopa 25 mg tablet, 100

<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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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
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<td>34.09</td>
<td>5.75</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</table>

### levdopa 250 mg + carbidopa 25 mg tablet, 100

<table>
<thead>
<tr>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>37.65</td>
<td>38.94</td>
<td>5.76</td>
<td>* APO-Levodopa/Carbidopa [TX] * SINADOPA 250/25 [RW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Sinemet [AL]</td>
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</table>

### LEVODOPA + CARBIDOPA

**Note:** Pharmaceutical benefits that have the form levdopa 200 mg + carbidopa 50 mg modified release tablet, 100 and pharmaceutical benefits that have the form levdopa 200 mg + carbidopa 50 mg modified release tablet, 60 are equivalent for the purposes of substitution.

**Note:** Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### levdopa 200 mg + carbidopa 50 mg modified release 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>1</td>
<td>5</td>
<td>67.88</td>
<td>41.00</td>
<td>* Sinemet CR [AL]</td>
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### levdopa 200 mg + carbidopa 50 mg modified release tablet, 60

<table>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>1.7</td>
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<td>*72.92</td>
<td>41.00</td>
<td>* Sinemet CR Prolonged-Release Tablets [OQ]</td>
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</table>

### LEVODOPA + CARBIDOPA

**Note:** Special Pricing Arrangements apply.

**Note:** Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note:** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

### Authority required (STREAMLINED)

#### 10197

**Advanced Parkinson disease**

**Treatment Phase:** Maintenance therapy

**Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must have been commenced on treatment in a hospital-based movement disorder clinic.
**LEVODOPA + CARBIDOPA**

**Note** Special Pricing Arrangements apply.

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

**Authority required (STREAMLINED)**

**10386**
Advanced Parkinson disease

**T**reatment Phase: Maintenance therapy

**Clinical criteria:**
- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must have been commenced on treatment in a hospital-based movement disorder clinic, **AND**
- Patient must require continuous administration of levodopa without an overnight break; OR
- Patient must require a total daily dose of more than 2000 mg of levodopa.

**LEVODOPA + CARBIDOPA + 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.

**Restricted benefit**
Parkinson disease

**Clinical criteria:**
- Patient must be being treated with levodopa decarboxylase inhibitor combinations, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

**Restricted benefit**
Parkinson disease

**Clinical criteria:**
- Patient must be stabilised on concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone.
**Adamantane derivatives**

- **AMANTADINE**
  
  **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.

- **Restricted benefit**
  
  Parkinson disease

  **Clinical criteria:**
  - The condition must not be drug induced.

  **amantadine hydrochloride 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>
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<tbody>
<tr>
<td>3016R</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>39.14</td>
<td>Symmetrel 100 [NV]</td>
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</tbody>
</table>

- **Dopamine agonists**

- **APOMORPHINE**
  
  **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.

  **Authority required (STREAMLINED)**

  **10844**

  Parkinson disease

  **Treatment Phase:** Maintenance therapy

  **Clinical criteria:**
  - Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
  - Patient must have been commenced on treatment in a specialist unit in a hospital setting.

  **apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials**

<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>12142C</td>
<td>18</td>
<td>5</td>
<td>..</td>
<td>*7604.46</td>
<td>Apomine Solution for Infusion [PF]</td>
</tr>
</tbody>
</table>

  **Note**
  - No increase in the maximum quantity or number of units may be authorised.

  **Note** Shared Care Model:
  
  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

  **Note** Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.

  **Authority required (STREAMLINED)**

  **10844**

  Parkinson disease

  **Treatment Phase:** Maintenance therapy

  **Clinical criteria:**
  - Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
  - Patient must have been commenced on treatment in a specialist unit in a hospital setting.

  **apomorphine hydrochloride hemihydrate 30 mg/3 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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<tr>
<td>12133N</td>
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<td>5</td>
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<td>*2764.94</td>
<td>Apomine Intermittent [PF]</td>
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</table>

  **apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices**

<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>12137T</td>
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<td>5</td>
<td>..</td>
<td>*2764.94</td>
<td>Movapo Pen [TD]</td>
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</tbody>
</table>

- **BROMOCRIPTINE**

  **Caution** Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

  **Restricted benefit**

  Acromegaly

  **Restricted benefit**

  Parkinson disease

  **Restricted benefit**

  Pathological hyperprolactinaemia
NERVOUS SYSTEM

Clinical criteria:
- Patient must be one in whom surgery is not indicated.

**Restricted benefit**
Pathological hyperprolactinaemia

Clinical criteria:
- Patient must have had surgery for this condition with incomplete resolution.

**Restricted benefit**
Pathological hyperprolactinaemia

Clinical criteria:
- Patient must be one in whom radiotherapy is not indicated.

**Restricted benefit**
Pathological hyperprolactinaemia

Clinical criteria:
- Patient must have had radiotherapy for this condition with incomplete resolution.

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>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2</td>
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**CABERGOLINE**

Caution
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**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.

**Restricted benefit**
Parkinson disease

cabergoline 1 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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<tr>
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<td>60.53</td>
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cabergoline 2 mg tablet, 30

<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>
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<td>5</td>
<td>..</td>
<td>77.04</td>
<td>41.00</td>
<td>Cabaser [PF]</td>
</tr>
</tbody>
</table>

**PRAMIPEXOLE**

Caution
Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**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.

**Restricted benefit**
Parkinson disease

pramipexole dihydrochloride monohydrate 1 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>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>90.07</td>
<td>41.00</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Sifrol [BY]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Simpral [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Pramipexole AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Simpex 1 [RW]</td>
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pramipexole dihydrochloride monohydrate 125 microgram tablet, 30

<table>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>14.75</td>
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<td></td>
<td></td>
<td></td>
<td>* Sifrol [BY]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Simpral [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Pramipexole AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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pramipexole dihydrochloride monohydrate 250 microgram tablet, 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>
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<td>29.90</td>
<td>31.19</td>
<td>* APO-Pramipexole [TX]</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Sifrol [BY]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Simpral [AF]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>* Pramipexole AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Simpex 0.25 [RW]</td>
</tr>
</tbody>
</table>

**PRAMIPEXOLE**

Caution
Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**

Parkinson disease

**PRAMIPEXOLE**

Caution Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note This drug is not PBS-subsidised for Restless Legs Syndrome secondary to other causes
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

**Clinical criteria:**

- Patient must manifest all 4 diagnostic criteria for Restless Legs Syndrome, **AND**
- Patient must have a baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score 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**

**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note** This drug is not PBS-subsidised for Restless Legs Syndrome secondary to other causes
**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Primary severe restless legs syndrome

**Clinical criteria:**

- Patient must manifest all 4 diagnostic criteria for Restless Legs Syndrome, **AND**
- Patient must have a baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score 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.
### 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>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>29.90</td>
<td>31.19</td>
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</table>

#### rotigotine 6 mg/24 hours patch, 28

<table>
<thead>
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<th>No. of Rpts</th>
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<tr>
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<td>..</td>
<td>93.58</td>
<td>41.00</td>
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#### rotigotine 8 mg/24 hours patch, 28

<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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<tr>
<td>1</td>
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<td>41.00</td>
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</table>

#### MONOAMINE OXIDASE B INHIBITORS

### RASAGILINE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### rasagiline 1 mg tablet, 30

<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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<tr>
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<td>86.62</td>
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<td>* Azilect [TB]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Pharmacor Rasagiline [CR]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Rasagiline-Teva [EV]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Rasalect [TI]</td>
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</tbody>
</table>

### SAFINAMIDE

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### safinamide 50 mg tablet, 30

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<tr>
<th>Max Qty Packs</th>
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</tbody>
</table>

#### safinamide 100 mg tablet, 30

<table>
<thead>
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<tr>
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### SELEGILINE

**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 20 mg tablet, 30

<table>
<thead>
<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>1</td>
<td>5</td>
<td>..</td>
<td>17.34</td>
<td>41.00</td>
<td>Xadago [CS]</td>
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</tbody>
</table>
• The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

selegiline hydrochloride 5 mg tablet, 100

<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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<tr>
<td>1973W</td>
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<td>54.06</td>
<td>41.00</td>
<td>Eldepryl [AS]</td>
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</table>

Other dopaminergic agents

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.

Restricted benefit
Parkinson disease

Clinical criteria:
• The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, AND
• Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

entacapone 200 mg tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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</thead>
<tbody>
<tr>
<td>8367J</td>
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<td>226.56</td>
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PSYCHOLEPTICS

ANTISYPHOTICS

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.

chlorpromazine hydrochloride 50 mg/2 mL injection, 10 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>
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<td>1195X</td>
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<td>21.94</td>
<td>23.23</td>
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</table>

chlorpromazine hydrochloride 5 mg/mL oral liquid, 100 mL

<table>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>1201F</td>
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<td>17.80</td>
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chlorpromazine hydrochloride 10 mg tablet, 100

<table>
<thead>
<tr>
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<td>16.45</td>
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chlorpromazine hydrochloride 100 mg tablet, 100

<table>
<thead>
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<th>No. of Rpts</th>
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chlorpromazine hydrochloride 25 mg tablet, 100

<table>
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<tr>
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PHENOTHIAZINES WITH PIPERIDINE STRUCTURE

PERICIAZINE

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.

periciazine 10 mg tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tbody>
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<td>18.22</td>
<td>19.51</td>
<td>Neulactil [SW]</td>
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periciazine 2.5 mg tablet, 100

<table>
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<tbody>
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<td>16.32</td>
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Butyrophenone derivatives
HALOPERIDOL

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

haloperidol 5 mg/mL injection, 10 x 1 mL ampoules
2768Q

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>23.22</td>
<td></td>
<td>24.51</td>
<td>Serenace [AS]</td>
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</table>

haloperidol 2 mg/mL oral liquid, 100 mL
2763K

<table>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>$1</td>
<td>5</td>
<td>22.54</td>
<td></td>
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haloperidol 1.5 mg tablet, 100
2767P

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<tbody>
<tr>
<td></td>
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haloperidol 5 mg tablet, 50
2770T

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<tr>
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<td></td>
<td>16.83</td>
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<td>Serenace [AS]</td>
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haloperidol 500 microgram tablet, 100
2761H

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<tr>
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<td></td>
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<td>Serenace [AS]</td>
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</table>

HALOPERIDOL DECANOATE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

haloperidol (as decanoate) 150 mg/3 mL injection, 5 x 3 mL ampoules
2766N

<table>
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<tbody>
<tr>
<td></td>
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<td>41.00</td>
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<td>Haldol decanoate [JC]</td>
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</tbody>
</table>

haloperidol (as decanoate) 50 mg/mL injection, 5 x 1 mL ampoules
2765M

<table>
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</table>

Indole derivatives

LURASIDONE

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.

Authority required (STREAMLINED)
4246
Schizophrenia

lurasidone hydrochloride 40 mg tablet, 30
10526B

<table>
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<tr>
<th>Max Qty Packs</th>
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<td></td>
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<td>Lurasidone Lupin [GQ]</td>
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lurasidone hydrochloride 80 mg tablet, 30
10529E

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<td>41.00</td>
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<td></td>
<td>Lurasidone Lupin [GQ]</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Pharmacor Lurasidone [CR]</td>
</tr>
</tbody>
</table>

ZIPRASIDONE

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.

Authority required (STREAMLINED)
4246
Schizophrenia

Authority required (STREAMLINED)
Acute mania or mixed episodes
Clinical criteria:
- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as monotherapy, **AND**
- The treatment must be limited to up to 6 months per episode.

<table>
<thead>
<tr>
<th>ziprasidone 20 mg capsule, 60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
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<tr>
<td>9070J</td>
</tr>
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<table>
<thead>
<tr>
<th>ziprasidone 40 mg capsule, 60</th>
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</thead>
<tbody>
<tr>
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</tbody>
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<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
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<td>Max Qty Packs</td>
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<tr>
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<table>
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<tr>
<th>ziprasidone 80 mg capsule, 60</th>
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<tbody>
<tr>
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</tr>
<tr>
<td>9073M</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Thioxanthene derivatives

### FLUPENTIXOL 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>Flupentixol decanoate 100 mg/mL injection, 5 x 1 mL ampoules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2257T</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flupentixol decanoate 20 mg/mL injection, 5 x 1 mL ampoules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2255Q</td>
</tr>
</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.

<table>
<thead>
<tr>
<th>Zuclopenthixol decanoate 200 mg/mL injection, 5 x 1 mL ampoules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>8097E</td>
</tr>
</tbody>
</table>

Diazepines, oxazepines, thiazepines and oxepines

### ASENAPINE

*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.

**Authority required (STREAMLINED)**

4246
Schizophrenia

**Authority required (STREAMLINED)**

5773
Acute mania or mixed episodes

Clinical criteria:
- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be limited to up to 6 months per episode.
**NERVOUS SYSTEM**

Bipolar I disorder

**Clinical criteria:**
- The treatment must be maintenance therapy, **AND**
- The treatment must be as monotherapy.

### asenapine 10 mg sublingual wafer, 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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>234.74</td>
<td>41.00</td>
<td>Saphris [OQ]</td>
</tr>
</tbody>
</table>

### asenapine 5 mg sublingual wafer, 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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>143.63</td>
<td>41.00</td>
<td>Saphris [OQ]</td>
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</tbody>
</table>

### OLANZAPINE

**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.

**Authority required (STREAMLINED)**

5856
Schizophrenia

**Authority required (STREAMLINED)**

5869
Bipolar I disorder

**Clinical criteria:**
- The treatment must be maintenance therapy.

#### olanzapine 2.5 mg tablet, 28

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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>1</td>
<td>5</td>
<td>..</td>
<td>14.79</td>
<td>16.08</td>
<td></td>
</tr>
</tbody>
</table>

**Note** Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
**NERVOUS SYSTEM**

**General Pharmaceutical Benefits**

**Authority required (STREAMLINED)**

**5856**

Schizophrenia

**Authority required (STREAMLINED)**

**5869**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

---

**olanzapine 5 mg orally disintegrating tablet, 28**

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<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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<td>17.50</td>
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</tr>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td>Olanzapine ODT generichealth [GQ]</td>
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<tr>
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<td></td>
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<td></td>
<td></td>
<td>Olanzapine Sandoz ODT 5 [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PRYZEX ODT [RW]</td>
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</table>

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**olanzapine 5 mg wafer, 28**

<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>17.50</td>
<td>18.79</td>
<td>18.79</td>
<td>Zypine ODT [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Zyprexa Zydis [LY]</td>
</tr>
</tbody>
</table>

---

**OLANZAPINE**

**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.

**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.

---

**Authority required (STREAMLINED)**

**5856**

Schizophrenia

**Authority required (STREAMLINED)**

**5869**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.

---

**olanzapine 10 mg orally disintegrating tablet, 28**

<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>3382B</td>
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<td>24.38</td>
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<td>APO-Olanzapine ODT [TX]</td>
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<td></td>
<td>Olanzapine ODT generichealth [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>Olanzapine Sandoz ODT 10 [SZ]</td>
</tr>
<tr>
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<td>PRYZEX ODT [RW]</td>
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**olanzapine 10 mg wafer, 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>
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<td>24.38</td>
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<td>Zyprexa Zydis [LY]</td>
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</tbody>
</table>

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**OLANZAPINE**

**Note**  Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

---

**Authority required (STREAMLINED)**

**5856**

Schizophrenia

**Authority required (STREAMLINED)**

**5869**

Bipolar I disorder

**Clinical criteria:**

- The treatment must be maintenance therapy.
## NERVOUS SYSTEM

### OLANZAPINE

**Note** Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.

**Note** Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

5856
Schizophrenia

5869
Bipolar I disorder

**Clinical criteria:**
- The treatment must be maintenance therapy.

### Authority required (STREAMLINED)

5856

### Authority required (STREAMLINED)

5869

### OLANZAPINE

**Caution** Monitor for post-injection syndrome for at least two hours after each injection.

**Note** Special Pricing Arrangements apply.

**Note** Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

4304

### OLANZAPINE

**Caution** Monitor for post-injection syndrome for at least two hours after each injection.

**Note** Special Pricing Arrangements apply.

**Note** Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

4304

### QUETIAPINE

**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.

#### Authority required (STREAMLINED)

4246

### QUETIAPINE

**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.

#### Authority required (STREAMLINED)

4246

### QUETIAPINE

**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.

#### Authority required (STREAMLINED)

4246

### QUETIAPINE

**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.

#### Authority required (STREAMLINED)

4246

### OLANZAPINE

**Note** Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.

**Note** Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

5856
Schizophrenia

5869
Bipolar I disorder

**Clinical criteria:**
- The treatment must be maintenance therapy.

### Authority required (STREAMLINED)

5856

### Authority required (STREAMLINED)

5869

### OLANZAPINE

**Caution** Monitor for post-injection syndrome for at least two hours after each injection.

**Note** Special Pricing Arrangements apply.

**Note** Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

4304

### OLANZAPINE

**Caution** Monitor for post-injection syndrome for at least two hours after each injection.

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**Note** Shared Care Model:
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#### Authority required (STREAMLINED)

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### OLANZAPINE

**Caution** Monitor for post-injection syndrome for at least two hours after each injection.

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#### Authority required (STREAMLINED)

4304

### QUETIAPINE

**Note** Shared Care Model:
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#### Authority required (STREAMLINED)

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### QUETIAPINE

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#### Authority required (STREAMLINED)

4246

### QUETIAPINE

**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.

#### Authority required (STREAMLINED)

4246

# Schedule of Pharmaceutical Benefits – December 2020
- The treatment must be limited to up to 6 months per episode.

**Authority required (STREAMLINED)**

**5639**

Bipolar I disorder

**Clinical criteria:**
- The treatment must be maintenance therapy.

### quetiapine 150 mg modified release tablet, 60

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>APO-Quetiapine XR [TY]</td>
<td>APX-Quetiapine XR [RW]</td>
</tr>
<tr>
<td>Quetia XR [OW]</td>
<td>Tevatiapine XR [SZ]</td>
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</table>

### quetiapine 200 mg modified release tablet, 60

<table>
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<tr>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
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<td>APO-Quetiapine XR [TY]</td>
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<tr>
<td>QUETINE XR [RF]</td>
<td>QUETIANE-AS XR [RW]</td>
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<tr>
<td>Quetia XR [OW]</td>
<td>Tevatiapine XR [SZ]</td>
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</tbody>
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### quetiapine 300 mg modified release tablet, 60

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>APO-Quetiapine XR [TY]</td>
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</tr>
<tr>
<td>QUETINE XR [RF]</td>
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<tr>
<td>Quetia XR [OW]</td>
<td>Tevatiapine XR [SZ]</td>
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### quetiapine 400 mg modified release tablet, 60

<table>
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<th>Brand Name and Manufacturer</th>
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</thead>
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<td>APO-Quetiapine XR [TY]</td>
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</tr>
<tr>
<td>QUETINE XR [RF]</td>
<td>QUETIANE-AS XR [RW]</td>
</tr>
<tr>
<td>Quetia XR [OW]</td>
<td>Tevatiapine XR [SZ]</td>
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### quetiapine 50 mg modified release tablet, 60

<table>
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<td>QUETINE XR [RF]</td>
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### quetiapine 100 mg tablet, 90

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</thead>
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<tr>
<td>Kaptan [ER]</td>
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</tr>
<tr>
<td>Quetia 200 [RW]</td>
<td>Quetia AN [EA]</td>
</tr>
<tr>
<td>Kaptan-DRILA [RA]</td>
<td>Tevatiapine Sandoz Pharma [HX]</td>
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</tbody>
</table>

### quetiapine 200 mg tablet, 60

<table>
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<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
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<td>APO-Quetiapine [TX]</td>
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<td>Pharmanor Quetiapine 100 [CR]</td>
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<td>Quetiapine Actavis 200 [ED]</td>
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<td>Quetiapine APOTEX [GX]</td>
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<td>Quetiapine GH 200 [GQ]</td>
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<td>Quetiapine Sandoz [SZ]</td>
<td>Syquet [AF]</td>
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### quetiapine 300 mg tablet, 60

<table>
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<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>APO-Quetiapine [TX]</td>
<td>Kaptan [ER]</td>
</tr>
<tr>
<td>Pharmanor Quetiapine 200 [CR]</td>
<td>Quetia 200 [RW]</td>
</tr>
<tr>
<td>Quetiapine Actavis 200 [ED]</td>
<td>Quetia AN [EA]</td>
</tr>
<tr>
<td>Quetiapine APOTEX [GX]</td>
<td>Quetia-DRILA [RA]</td>
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<td>Quetiapine GH 200 [GQ]</td>
<td>Tevatiapine RBX [RA]</td>
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<td>Quetia Sandoz Pharma [HX]</td>
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<tr>
<td>Syquet [AF]</td>
<td>Seroquel [AP]</td>
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<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>APO-Quetiapine [TX]</td>
<td>Kaptan [ER]</td>
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<td>Pharmanor Quetiapine 300 [CR]</td>
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</tr>
<tr>
<td>Quetiapine Actavis 300 [ED]</td>
<td>Quetia AN [EA]</td>
</tr>
</tbody>
</table>
**NERVOUS SYSTEM**

- **QUETIAPINE**
  - **Note:** No increase in the maximum quantity or number of units may be authorised.
  - **Note:** Authority applications for increased repeats up to a maximum of 5 may be authorised for patients requiring dose optimisation for this condition not adequately provided by other strengths of this drug.

  - **Shared Care Model:** For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

  - **Authority required (STREAMLINED)**
    - **7916** Schizophrenia
    - **7927** Acute mania

  - **Clinical criteria:**
    - The condition must be associated with bipolar I disorder, **AND**
    - The treatment must be as monotherapy.

  - **Authority required (STREAMLINED)**
    - **7893** Bipolar I disorder

  - **Clinical criteria:**
    - The treatment must be maintenance therapy.

  - **quetiapine 25 mg tablet, 60**
    - **8456C**

  - **Benzamides**

- **AMISULPRIDE**
  - **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.

  - **Authority required (STREAMLINED)**
    - **4246** Schizophrenia

  - **amisulpride 100 mg/mL oral liquid, 60 mL**
    - **8736T**

  - **amisulpride 100 mg tablet, 30**
    - **8594H**

  - **amisulpride 200 mg tablet, 60**
    - **8595J**

---

Schedule of Pharmaceutical Benefits – December 2020
NERVOUS SYSTEM

General Pharmaceutical Benefits

**amisulpride 400 mg tablet, 60**

<table>
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<th>8596K</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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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>
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<td>* Amisulpride 400 Winthrop [WA]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Amisulpride AN [EA]</td>
<td>* Amisulpride Sandoz [SZ]</td>
<td></td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Amisulpride Sandoz Pharma [HK]</td>
<td>* APO-Amisulpride [TX]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Solian 400 [SW]</td>
<td>* Sulpiri [AF]</td>
<td></td>
</tr>
</tbody>
</table>

* Other antipsychotics

**ARIPIPRAZOLE**

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.

**Authority required (STREAMLINED)**

4246

Schizophrenia

**aripiprazole 15 mg tablet, 30**

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**aripiprazole 20 mg tablet, 30**

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**aripiprazole 30 mg tablet, 30**

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<td>* Aripiprazole generichealth [HQ]</td>
<td>* Aripiprazole GH [GQ]</td>
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<td>* Aripiprazole Sandoz [SZ]</td>
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**aripiprazole 300 mg modified release injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack**

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**aripiprazole 400 mg modified release injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack**

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**aripiprazole 10 mg tablet, 30**

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<tr>
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<td>* APO-Aripiprazole [TX]</td>
<td>* Aripiprazole AN [EA]</td>
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<td>* Aripiprazole generichealth [HQ]</td>
<td>* Aripiprazole GH [GQ]</td>
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<td>* Aripiprazole Sandoz [SZ]</td>
<td>* Tevaripiprazole [TB]</td>
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**BREXIPIPRAZOLE**

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.

**Authority required (STREAMLINED)**

4246

Schizophrenia
### NERVOUS SYSTEM

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<td>41.00</td>
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### PALIPERIDONE

**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.

**Authority required (STREAMLINEd)**

| Paliperidone 100 mg modified release injection, 1 syringe | 5107T | 5 | .. | 380.73 | 41.00 | Invega Sustenna [JC] |
| Paliperidone 150 mg modified release injection, 1 syringe | 5109X | 5 | .. | 380.73 | 41.00 | Invega Sustenna [JC] |
| Paliperidone 25 mg modified release injection, 1 syringe | 5100K | 5 | .. | 123.91 | 41.00 | Invega Sustenna [JC] |
| Paliperidone 50 mg modified release injection, 1 syringe | 5102M | 5 | .. | 240.77 | 41.00 | Invega Sustenna [JC] |
| Paliperidone 75 mg modified release injection, 1 syringe | 5103N | 5 | .. | 311.11 | 41.00 | Invega Sustenna [JC] |
| Paliperidone 3 mg modified release tablet, 28 | 9140C | 5 | .. | 68.90 | 41.00 | Invega [JC] |
| Paliperidone 6 mg modified release tablet, 28 | 9141D | 5 | .. | 127.69 | 41.00 | Invega [JC] |
| Paliperidone 9 mg modified release tablet, 28 | 9142E | 5 | .. | 188.01 | 41.00 | Invega [JC] |

**Note** Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Patient dosage is to be determined as per the dose transition table in the Product Information based on the maintenance dose of paliperidone once monthly injection.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Authority required (STREAMLINEd)**

| 6832 |
Schizophrenia

Clinical criteria:
- Patient must have previously received and be stabilised on PBS-subsidised paliperidone once-monthly injection for at least 4 consecutive months.

<p>| paliperidone 175 mg/0.875 mL modified release injection, 0.875 mL syringe |</p>
<table>
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<tr>
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<th>Premium $</th>
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<td>708.28</td>
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<p>| paliperidone 263 mg/1.315 mL modified release injection, 1.315 mL syringe |</p>
<table>
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<p>| paliperidone 350 mg/1.75 mL modified release injection, 1.75 mL syringe |</p>
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<td>1123.17</td>
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<p>| paliperidone 525 mg/2.625 mL modified release injection, 2.625 mL syringe |</p>
<table>
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**Risperidone**

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.

**Authority required (STREAMLINED)**

4246
Schizophrenia

**Authority required (STREAMLINED)**

5907
Acute Mania

Clinical criteria:
- The condition must be associated with bipolar I disorder, **AND**
- The treatment must be as adjunctive therapy to mood stabilisers, **AND**
- The treatment must be limited to up to 6 months per episode.

<p>| risperidone 1 mg/mL oral liquid, 100 mL |</p>
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<p>| risperidone 1 mg tablet, 60 |</p>
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<p>| risperidone 3 mg tablet, 60 |</p>
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**Risperidone**

**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.

### Authority required (STREAMLINED)

6898
Severe behavioural disturbances

**Clinical criteria:**
- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**
- Patient must be under 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 spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

### Authority required (STREAMLINED)

6899
Severe behavioural disturbances

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**
- Patient must be aged 18 years or older.
- 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 spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

### Risperidone 4 mg tablet, 60

Max Qty packs 3172Y

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### Risperidone 1 mg/mL oral liquid, 100 mL

Max Qty packs 9293D

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### Risperidone 1 mg tablet, 60

Max Qty packs 8789N

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**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Authority required (STREAMLINED)

6897
Severe behavioural disturbances

**Clinical criteria:**
- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
NERVOUS SYSTEM

- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**
- Patient must be under 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 spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority required (STREAMLINED)**
6938
Severe behavioural disturbances
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**
- Patient must be aged 18 years or older.
- 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 spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

---

**RISPERIDONE**

**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.

**Authority required (STREAMLINED)**
4246
Schizophrenia

**Authority required (STREAMLINED)**
5912
Bipolar I disorder

**Clinical criteria:**
- The condition must be refractory to treatment, **AND**
- The treatment must be in combination with lithium or sodium valproate, **AND**
- The treatment must be maintenance therapy.

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**risperidone 2 mg tablet, 60**
9079W

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**risperidone 25 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**
8780D

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**risperidone 37.5 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**
8781E

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**risperidone 50 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**
8782F

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**RISPERIDONE**

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note**
For item codes 8869T and 1846E, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

---

General Pharmaceutical Benefits 851
NERVOUS SYSTEM

risperidone 500 microgram tablet, 20
1846E

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risperidone 500 microgram tablet, 60
8869T

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### RISPERIDONE

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note**
For items 8787L and 1842Y, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

6898
Severe behavioural disturbances

**Clinical criteria:**
- Patient must have autism spectrum disorder, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**
- Patient must be under 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 spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Authority required (STREAMLINED)**

6899
Severe behavioural disturbances

Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have autism spectrum disorder, **AND**
- Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, **AND**
- The treatment must be under the supervision of a paediatrician or psychiatrist, **AND**
- The treatment must be in combination with non-pharmacological measures.

**Population criteria:**
- Patient must be aged 18 years or older.

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 spectrum disorder must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) or ICD-10 international classification of mental and behavioural disorders.

**Caution**
In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical...
practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the
Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**10020**

Behavioural disturbances

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A patient may only qualify for 12 weeks of PBS-subsidised treatment under this restriction once in a 12 month period.

**Risperidone 1 mg/mL oral liquid, 100 mL**

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**Risperidone 1 mg tablet, 60**

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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.

**Note** Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

Behavioural disturbances

**Treatment Phase: Continuing treatment, trial of dose reduction or cessation of treatment**

**Clinical criteria:**

- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have responded to an initial course of treatment with this drug for this condition, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- The treatment must be for dose tapering purposes as part of a trial of treatment reduction or cessation; OR
- Patient must have trialled a period of treatment reduction or cessation with this drug for this condition and experienced worsening or re-emergence of symptoms during this trial, and retrials are considered periodically, **AND**
- Patient must be optimised on non-pharmacological methods of treatment.

The patient's response to treatment and a trial of treatment reduction or cessation must be discussed formally with a psychiatrist or geriatrician or in a documented clinical review process involving at least one other medical practitioner, or be reviewed by a psychiatrist or geriatrician.

Response to treatment is defined as a significant reduction in symptoms of psychosis or aggression.

Patients must cease treatment if there is no improvement in symptoms of psychosis and aggression, or worsening of symptoms with therapy.

Patients must be monitored for adverse effects such as falls, drowsiness leading to reduced self-care, incontinence, reduced nutrition, reduced ability to communicate needs/wishes and take part in activities. Therapy must be ceased if harms of therapy outweigh benefits.

Trials of reduction or cessation of therapy should be considered periodically with the intention of maintaining symptom control through non-pharmacological measures wherever possible and/or lowest effective dose therapy.

Evidence of patient benefit from therapy, failure of non-pharmacological approaches to manage symptoms in the absence of therapy, and recurrence of symptoms following reduction or cessation of therapy, trialled on at least 1 occasion, must be documented in the patient's medical records.
### 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.

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note**
Pharmaceutical benefits that have the form pack size risperidone 500 microgram tablet, 20 and pharmaceutical benefits that have the form pack size risperidone 500 microgram tablet, 60 are equivalent for the purposes of substitution.

**Note**
No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**10020**

Behavioural disturbances

**Clinical criteria:**
- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A patient may only qualify for 12 weeks of PBS-subsidised treatment under this restriction once in a 12 month period.

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### risperidone 1 mg/mL oral liquid, 100 mL

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<th>Brand Name and Manufacturer</th>
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### risperidone 1 mg tablet, 60

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### risperidone 500 microgram tablet, 20

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### risperidone 500 microgram tablet, 60

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<tr>
<td>* Risperidone Sandoz [SZ]</td>
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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.

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note**
Pharmaceutical benefits that have the form pack size risperidone 500 microgram tablet, 20 and pharmaceutical benefits that have the form pack size risperidone 500 microgram tablet, 60 are equivalent for the purposes of substitution.

**Note**
No increase in the maximum number of repeats may be authorised.

---

### Authority required

**Behavioural disturbances**

**Clinical criteria:**
- The condition must be characterised by psychotic symptoms and aggression, **AND**
- Patient must have dementia of the Alzheimer type, **AND**
- Patient must have responded to an initial course of treatment with this drug for this condition, **AND**
- Patient must have failed to respond to non-pharmacological methods of treatment, **AND**
The treatment must be for dose tapering purposes as part of a trial of treatment reduction or cessation; OR
Patient must have trialled a period of treatment reduction or cessation with this drug for this condition and experienced worsening or re-emergence of symptoms during this trial, and retrials are considered periodically, AND
Patient must be optimised on non-pharmacological methods of treatment.
The patient's response to treatment and a trial of treatment reduction or cessation must be discussed formally with a psychiatrist or geriatrician or in a documented clinical review process involving at least one other medical practitioner, or be reviewed by a psychiatrist or geriatrician.
Response to treatment is defined as a significant reduction in symptoms of psychosis or aggression.
Patients must cease treatment if there is no improvement in symptoms of psychosis and aggression, or worsening of symptoms with therapy.
Patients must be monitored for adverse effects such as falls, drowsiness leading to reduced self-care, incontinence, reduced nutrition, reduced ability to communicate needs/wishes and take part in activities. Therapy must be ceased if harms of therapy outweigh benefits.
Trials of reduction or cessation of therapy should be considered periodically with the intention of maintaining symptom control through non-pharmacological measures wherever possible and/or lowest effective dose therapy.
Evidence of patient benefit from therapy, failure of non-pharmacological approaches to manage symptoms in the absence of therapy, and recurrence of symptoms following reduction or cessation of therapy, trialled on at least 1 occasion, must be documented in the patient's medical records.

### ANXIOLYSES

#### BENZODIAZEPINE DERIVATIVES

### ALPRAZOLAM

**Note** The panic disorder must not be attributable to some known organic factor.
**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required

**Panic disorder**

**Clinical criteria:**
- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

#### DIAZEPAM

**Note** Authority required

---

<table>
<thead>
<tr>
<th>Medication</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>
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<td><strong>Risperone Sandoz [SZ]</strong></td>
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**General Pharmaceutical Benefits**

855
### Chronic spasticity

**Population criteria:**
- Patient must be under 18 years of age.

#### Diazepam 1 mg/mL oral liquid, 100 mL

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<tr>
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#### 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.
NERVOUS SYSTEM

General Pharmaceutical Benefits

• Patient must be receiving long-term nursing care, **AND**
• Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
• Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

oxazepam 15 mg tablet, 25
3134Y

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<tbody>
<tr>
<td>2</td>
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oxazepam 30 mg tablet, 25
3135B

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<tr>
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<td>*14.18</td>
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<td></td>
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<td>*4.66</td>
<td>*18.84</td>
<td>* Murelax [RW]</td>
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<td></td>
<td>* Serepax [AS]</td>
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HYPNOTICS AND SEDATIVES

Benzodiazepine derivatives

• NITRAZEPAM

nitrAzepam 5 mg tablet, 25
5189D

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<td>14.92</td>
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• NITRAZEPAM

Note

Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of nitrazepam.

nitrAzepam 5 mg tablet, 25
2723H

<table>
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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>..</td>
<td>13.63</td>
<td>14.92</td>
<td>Mogadon [IL]</td>
</tr>
</tbody>
</table>

• NITRAZEPAM

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Myoclonic epilepsy

Authority required

Malignant neoplasia (late stage)

Authority required

Insomnia

Clinical criteria:

• Patient must be receiving this drug for the management of insomnia, **AND**
• Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
• Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

Authority required

Insomnia

Clinical criteria:

• Patient must be receiving this drug for the management of insomnia, **AND**
• Patient must be receiving long-term nursing care, **AND**
• Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
• Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

nitrAzepam 5 mg tablet, 25
2732T

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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>5</td>
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<td>*15.24</td>
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• TEMAZEPAM

temazepam 10 mg tablet, 25
5221T

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<td>* Temaze [AF]</td>
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<td>* Temtabs [LN]</td>
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**NERVOUS SYSTEM**

### TEMAZEPAM

**Note** Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the ‘Authority required’ listing of temazepam.

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**TEMAZEPAM**

**Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**

Malignant neoplasia (late stage)

**Authority required**

Insomnia

**Clinical criteria:**
- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

**Authority required**

Insomnia

**Clinical criteria:**
- Patient must be receiving this drug for the management of insomnia, **AND**
- Patient must be receiving long-term nursing care, **AND**
- Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, **AND**
- Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

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### PSYCHOANALEPTICS

### ANTIDEPRESSANTS

**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.

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**NERVOUS SYSTEM**

### CLOMIPRAMINE

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<tr>
<th>Restricted benefit</th>
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<tbody>
<tr>
<td>Cataplexy</td>
</tr>
</tbody>
</table>

**Clinical criteria:**
- The condition must be associated with narcolepsy.

<table>
<thead>
<tr>
<th>Restricted benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obsessive-compulsive disorder</td>
</tr>
<tr>
<td>Phobic disorders</td>
</tr>
</tbody>
</table>

**Population criteria:**
- Patient must be an adult.

**clomipramine hydrochloride 25 mg tablet, 50**

<table>
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<th>No. of Rpts</th>
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<td>* GenRx Clomipramine [GX]</td>
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### DOSULEPIN (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.

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<tr>
<td>1357K</td>
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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.

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<th>doxepin 10 mg capsule, 50</th>
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<tbody>
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<td>1011F</td>
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<table>
<thead>
<tr>
<th>doxepin 25 mg capsule, 50</th>
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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.

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2420J</td>
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</tbody>
</table>
**IMIPRAMINE**

*Note* Pharmaceutical benefits that have the form imipramine hydrochloride 25 mg tablet in a pack size of 50 can be substituted for a pack size of 100 in the case of a shortage.

*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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**NORTRIPTYLINE**

*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.

**Restricted benefit**

*Major depression*

**Clinical criteria:**
- The treatment must be for use when other anti-depressant therapy has failed.

**Restricted benefit**

*Major depression*

**Clinical criteria:**
- The treatment must be for use when other anti-depressant therapy is contraindicated.

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**Selective serotonin reuptake inhibitors**

**CITALOPRAM**

**Restricted benefit**

*Major depressive disorders*

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**ESCITALOPRAM**

**Restricted benefit**

*Major depressive disorders*
- **ESCITALOPRAM**
  
  **Restricted benefit**
  Moderate to severe generalised anxiety disorder (GAD)

  **Clinical criteria:**
  - The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND
  - Patient must not have responded to non-pharmacological therapy, AND
  - Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

  **Restricted benefit**
  Moderate to severe generalised anxiety disorder (GAD)

  **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.

  **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 have not responded to non-pharmacological therapy, AND
  - Patient must have been assessed by a psychiatrist.

- **ESCITALOPRAM**
  
  **Restricted benefit**
  Major depressive disorders

  **Restricted benefit**
  Moderate to severe generalised anxiety disorder (GAD)

  **Clinical criteria:**
The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, 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,
- Patient must not have responded to non-pharmacological therapy,
- 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,
- Patient must not have responded to non-pharmacological therapy,
- 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,
- Patient must not have responded to non-pharmacological therapy,
- Patient must have been assessed by a psychiatrist.

---

**FLUOXETINE**

**Restricted benefit**

Major depressive disorders

**Restricted benefit**

Obsessive-compulsive disorder

**escitalopram 20 mg/mL oral liquid, 15 mL**

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<td>Flvox [AL]</td>
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<td>Zactin [AF]</td>
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**fluoxetine 20 mg tablet, 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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<tr>
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**fluvoxamine maleate 50 mg tablet, 30**

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</table>
**Nervous System**

### PAROXETINE

**Restricted benefit**

- Major depressive disorders
- Obsessive-compulsive disorder
- Panic disorder

**Paroxetine 20 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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**Paroxetine 50 mg tablet, 30**

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### SERTRALINE

**Restricted benefit**

- Major depressive disorders
- Obsessive-compulsive disorder
- Panic disorder

**Sertraline 100 mg tablet, 30**

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**Sertraline 50 mg tablet, 30**

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### SERTRALINE

**Restricted benefit**

- Obsessive-compulsive disorder
- Panic disorder

**Sertraline 100 mg tablet, 30**

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<td>Sertraline generichealth [GQ]</td>
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<td>Sertraline [RA]</td>
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**Monoamine oxidase inhibitors, non-selective**

### PHENELZINE

**Caution** This drug is an irreversible monoamine oxidase inhibitor.

**Restricted benefit**

- Depression

**Clinical criteria:**
- The treatment must be for when all other anti-depressant therapy has failed; OR
- The treatment must be for when all other anti-depressant therapy is inappropriate.

---

General Pharmaceutical Benefits 863
### NERVOUS SYSTEM

#### phenelzine 15 mg tablet, 100

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#### TRANYLCYPROMINE

**Caution** This drug is an irreversible monoamine oxidase inhibitor.

#### tranylcypromine 10 mg tablet, 50

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### Monoamine oxidase A inhibitors

#### MOCLOBEMIDE

**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.

**Restricted benefit**
Major depressive disorders

<table>
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<td>Clobemix [ED]</td>
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<td>Moclobemide Sandoz [SZ]</td>
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<td>Moclobemide AN [EA]</td>
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<td>Auroxir [GO]</td>
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<table>
<thead>
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<tr>
<th>Branch Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sandoz [SZ]</td>
</tr>
<tr>
<td>Pristiq [PF]</td>
</tr>
</tbody>
</table>

### Other antidepressants

#### DESVENLAFAXINE

**Note** Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.

**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.

**Restricted benefit**
Major depressive disorders

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desflax [AF]</td>
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<tr>
<td>Desvenlafaxine Actavis [EA]</td>
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<tr>
<td>Desvenlafaxine Sandoz [SZ]</td>
</tr>
<tr>
<td>APO-Desvenlafaxine MR [TX]</td>
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<tr>
<td>Desvenlafaxine GH XR [GQ]</td>
</tr>
<tr>
<td>Pristiq [PF]</td>
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</table>
### NERVOUS SYSTEM

#### desvenlafaxine 50 mg modified release tablet, 28

<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>
<th>Brand Name and Manufacturer</th>
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<td>APO-Desvenlafaxine MR [TX]</td>
<td>Desvenlafaxine GH XR [GQ]</td>
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#### desvenlafaxine 50 mg modified release tablet, 28

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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<td>22.19</td>
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<td>Desfai [AF]</td>
<td>Desvenlafaxine Actavis [EA]</td>
</tr>
<tr>
<td></td>
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<td>DESVEN [RW]</td>
<td>Desvenlafaxine Sandoz [SZ]</td>
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#### desvenlafaxine 50 mg modified release tablet, 28

<table>
<thead>
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<th>Max Qty</th>
<th>No. of Rpts</th>
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<th>MRVSN $</th>
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</table>

### DULOXETINE

**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.

**Restricted benefit**
Major depressive disorders

#### duloxetine 30 mg enteric capsule, 28

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<td>Duloxetine Sandoz 30 [SZ]</td>
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<td>DYTREX 30 [RW]</td>
<td>Tixol [AL]</td>
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### 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 450 mg modified release tablet, 100

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<tr>
<td>2</td>
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#### lithium carbonate 250 mg tablet, 200

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### MIANSERIN

**Caution** Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of 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.

**Restricted benefit**
Severe depression

#### mianserin hydrochloride 10 mg tablet, 50

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<th>MRVSN $</th>
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#### mianserin hydrochloride 20 mg tablet, 50

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</table>
NERVOUS SYSTEM

- MIRTAZAPINE
  
  **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.

  **Restricted benefit**
  
  Major depressive disorders

  ### mirtazapine 15 mg tablet, 30
  
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<td>MIRTAZANA [RF]</td>
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<td></td>
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<td></td>
<td>Axit 15 [AF]</td>
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</table>

  **Restricted benefit**
  
  Major depressive disorders

  ### mirtazapine 15 mg orally disintegrating tablet, 30
  
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<thead>
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<td>Mirtazapine Sandoz ODT 15</td>
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<td>Mirtazapine [SZ]</td>
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  **Restricted benefit**
  
  Major depressive disorders

  ### mirtazapine 30 mg tablet, 30
  
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<td></td>
<td>Mirtazon [RW]</td>
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</table>

  **Restricted benefit**
  
  Major depressive disorders

  ### mirtazapine 30 mg orally disintegrating tablet, 30
  
<table>
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<td>Mirtazapine Sandoz ODT 30</td>
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<td>Mirtazapine [SZ]</td>
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  **Restricted benefit**
  
  Major depressive disorders

  ### mirtazapine 45 mg tablet, 30
  
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<td>Mirtazapine AN [EA]</td>
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<td></td>
<td></td>
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<td></td>
<td>Mirtazapine Sandoz [SZ]</td>
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<td>Mirtazon [RW]</td>
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</table>

  **Restricted benefit**
  
  Major depressive disorders

  ### mirtazapine 45 mg orally disintegrating tablet, 30
  
<table>
<thead>
<tr>
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<td>Mirtazapine [SZ]</td>
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</table>

  **Restricted benefit**
  
  Major depressive disorders

- REBOXETINE
  
  **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.

  **Restricted benefit**
  
  Major depressive disorders

  ### reboxetine 4 mg tablet, 60
  
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  **Restricted benefit**
  
  Major depressive disorders

- VENLAFAXINE
  
  **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.

  **Restricted benefit**
  
  Major depressive disorders

  ### venlafaxine 150 mg modified release capsule, 28
  
<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>Blooms the Chemist</td>
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<td></td>
<td>Sandoz Venlafaxine XR [HX]</td>
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</table>
### NERVOUS SYSTEM

#### General Pharmaceutical Benefits

**Venlafaxine 37.5 mg modified release capsule, 28**

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<td>Venlafaxine AN SR [EA]</td>
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<td>Sandoz Venlafaxine XR [HX]</td>
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**Venlafaxine 75 mg modified release capsule, 28**

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<td>Efexor-XR [UJ]</td>
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</tbody>
</table>

### PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS

#### Centrally acting sympathomimetics

**ARMODAFINIL**

**Note** This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamfetamine sulfate or modafinil.

**Authority required**

**Narcolepsy**

**Treatment Phase: Initial 1 - treatment of narcolepsy without cataplexy**

**Treatment criteria:**

- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**

- The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, AND
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, AND
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, AND
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine 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 dexamfetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration. The authority application must be made in writing and must include the following:

- (a) a completed authority prescription form; and
- (b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and
- (c) details of the contraindication or intolerance to dexamfetamine sulfate; and
- (d) either:
  - (i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or
  - (ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

**Narcolepsy**

**Treatment Phase: Initial 2 - treatment of narcolepsy with cataplexy**

**Treatment criteria:**
• Must be treated by a qualified sleep medicine practitioner or neurologist.

Clinical criteria:
• The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
• The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, AND
• Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, AND
• Patient must have a definite history of cataplexy documented in their medical records for auditing purposes, AND
• Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine 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 dexamfetamine sulfate as specified in the TGA-approved Product Information.

Note
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Narcolepsy
Treatment Phase: Continuing or change of treatment

Clinical criteria:
• Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
• Patient must have previously received PBS-subsidised treatment with modafinil for this condition.

Note
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

armodafinil 50 mg tablet, 30
10922W

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
2 5 .. 106.86 41.00 Nuvigil [TB]

armodafinil 150 mg tablet, 30
10912H

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1 5 .. 156.38 41.00 Nuvigil [TB]

armodafinil 250 mg tablet, 30
10919Q

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 255.95 41.00 Nuvigil [TB]

■ ATOMOXETINE

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)
7876
Attention deficit hyperactivity disorder
Treatment Phase: Initial treatment

Treatment criteria:
• Must be treated by a paediatrician or psychiatrist.

Clinical criteria:
• The condition must be or have been diagnosed according to the DSM-5 criteria, AND
• Patient must have a contraindication to dexamfetamine, methylphenidate or lisdexamfetamine as specified in TGA-approved product information; OR
• Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamfetamine, methylphenidate or lisdexamfetamine 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 dexamfetamine, methylphenidate and lisdexamfetamine (not simultaneously).

Population criteria:
• Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

Authority required (STREAMLINED)
7890
Attention deficit hyperactivity disorder
Treatment Phase: Continuing treatment

Clinical criteria:
• Patient must have previously received PBS-subsidised treatment with this drug for this condition.

atomoxetine 10 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 80 mg capsule, 28

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• DEXAMFETAMINE
  
  Note Care must be taken to comply with the provisions of State/Territory law when prescribing 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.

  Authority required
  Attention deficit hyperactivity disorder
  Treatment must be in accordance with the law of the relevant State or Territory.

  Authority required
  Narcolepsy

dexamfetamine sulfate 5 mg tablet, 100

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• LISDEXAMFETAMINE
  
  Note Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

  Note Special Pricing Arrangements apply.

  Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

  Note The treatment must not exceed a maximum daily dose of 70 mg.

  Authority required
  Attention deficit hyperactivity disorder

  Clinical criteria:
  • Patient must require continuous coverage over 12 hours.
### NERVOUS SYSTEM

**Population criteria:**
- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

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### METHYLPHENIDATE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing 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.

**Authority required**
Attention deficit hyperactivity disorder

**Population criteria:**
- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Clinical criteria:**
- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, AND
- Patient must require continuous coverage over 12 hours.

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### METHYLPHENIDATE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing 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.

**Authority required**
Attention deficit hyperactivity disorder
Treatment must be in accordance with the law of the relevant State or Territory.
methylphenidate hydrochloride 10 mg tablet, 100
8839F

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**NM**

**METHYLPHENIDATE**

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

**Authority required**
Attention deficit hyperactivity disorder

**Population criteria:**
- Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

**Clinical criteria:**
- Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events, **AND**
- Patient must require continuous coverage over 8 hours.

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methylphenidate hydrochloride 60 mg modified release capsule, 30
12116Q

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**MODAFINIL**

**Note** This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamfetamine sulfate or armodafinil.

**Authority required**
Narcolepsy

**Treatment Phase:** Initial 1 - treatment of narcolepsy without cataplexy

**Treatment criteria:**
- Must be treated by a qualified sleep medicine practitioner or neurologist.

**Clinical criteria:**
- The treatment must be for use with therapy with dexamfetamine sulfate poses an unacceptable medical risk; **OR**
- The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, **AND**
- Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, **AND**
- Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); **OR**
- Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, **AND**
- Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The presence of any one of the following indicates treatment with dexamfetamine 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 dexamfetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.
The authority application must be made in writing and must include the following:
(a) a completed authority prescription form; and
(b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and
(c) details of the contraindication or intolerance to dexamfetamine sulfate; and
(d) either:
   (i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or
   (ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.
The polysomnography, MSLT or EEG test reports must be provided with the authority application.

Note
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Narcolepsy
Treatment Phase: Initial 2 - treatment of narcolepsy with cataplexy

Treatment criteria:
• Must be treated by a qualified sleep medicine practitioner or neurologist.

Clinical criteria:
• The treatment must be for use when therapy with dexamfetamine sulfate poses an unacceptable medical risk; OR
• The treatment must be for use when intolerance to dexamfetamine sulfate is of a severity to necessitate treatment withdrawal, AND
• Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, AND
• Patient must have a definite history of cataplexy documented in their medical records for auditing purposes, AND
• Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.
The presence of any one of the following indicates treatment with dexamfetamine 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 dexamfetamine sulfate as specified in the TGA-approved Product Information.

Note
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Narcolepsy
Treatment Phase: Continuing or change of treatment

Clinical criteria:
• Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
• Patient must have previously received PBS-subsidised treatment with armodafinil for this condition.

Note
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

modafinil 100 mg tablet, 60
8816B

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ANTI-DEMENTIA DRUGS

Anticholinesterases

DONEPEZIL

Authority required
Mild to moderately severe Alzheimer disease
Treatment Phase: Initial 2

Clinical criteria:
General Pharmaceutical Benefits

11924N

Donepezil hydrochloride 10 mg tablet, 28

Max.Qty Packs  No. of Rpts  Premium $  DPMQ $  MRVSN $  Brand Name and Manufacturer  Brand Name and Manufacturer

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1  5  31.08  23.37  3.68  Arazil APN 10 [RF]  Donepezil-DRLA [RZ]

Donepezil hydrochloride 5 mg tablet, 28

Max.Qty Packs  No. of Rpts  Premium $  DPMQ $  MRVSN $  Brand Name and Manufacturer  Brand Name and Manufacturer

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1  5  25.76  23.37  3.68  Arazil APN 5 [RF]  Donepezil-DRLA [RZ]

Donepezil AN [EA]

Aridon 5 [RW]

Aridon APN 5 [RF]

Arazil [AF]

Arazil APN 10 [RF]

Donepezil-DRLA [RZ]

Donepezil Sandoz [SZ]

Donepezil Sandoz [SZ]

Donepezil [TX]

Donepezil GH [HQ]

Donepezil-DRLA [RZ]

Donepezil Sandoz [SZ]

Donepezil [TX]

Donepezil GH [HQ]

Donepezil-DRLA [RZ]

Donepezil Sandoz [SZ]

- DONEPEZIL

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

10108

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 has received a written authority approval, AND

- 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.

Application through this treatment restriction must be made in writing.

Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month's therapy and sufficient repeats to complete 6 months' initial treatment with this strength of this drug will be authorised under this restriction.

Where no prior approval has been issued before this application, up to a maximum of 1 month’s therapy plus 5 repeats will be authorised.

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial 2

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.

Application through this treatment restriction must be made in writing.

Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month’s therapy and sufficient repeats to complete 6 months’ initial treatment with this strength of this drug will be authorised under this restriction.

Where no prior approval has been issued before this application, up to a maximum of 1 month’s therapy plus 5 repeats will be authorised.


- 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;
- Patient's functional impairment, including but not limited to care of self, personal hygiene, and mobility.

**Donepezil hydrochloride 10 mg tablet, 28**

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**Donepezil hydrochloride 5 mg tablet, 28**

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**DONEPEZIL**

**Authority required**

Mild to moderately severe Alzheimer disease

**Treatment Phase: Initial 1**

**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.

Up to a maximum of 2 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction.

This 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 with this drug with this strength.

**Authority required**

Mild to moderately severe Alzheimer disease

**Treatment Phase: Initial 1**

**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.

Up to a maximum of 2 months’ initial therapy will be authorised for this drug, for this strength under this treatment restriction.

This 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 with this drug with this strength.
### GALANTAMINE

#### Authority required

Mild to moderately severe Alzheimer disease

**Treatment Phase: Initial** 2

**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. Application through this treatment restriction must be made in writing.

Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month’s therapy and sufficient repeats to complete 6 months’ initial treatment with this strength of this drug will be authorised under this restriction.

Where no prior approval has been issued before this application, 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** 2

**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.

Application through this treatment restriction must be made in writing.

Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month’s therapy and sufficient repeats to complete 6 months’ initial treatment with this strength of this drug will be authorised under this restriction.

Where no prior approval has been issued before this application, up to a maximum of 1 month’s therapy plus 5 repeats will be authorised.

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**NERVOUS SYSTEM**
galantamine 24 mg modified release capsule, 28
11899G

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**GALANTAMINE**

**Note Continuing Therapy Only:**
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

10108
Mild to moderately severe Alzheimer disease

**Clinical criteria:**
- Patient must have received six months of sole PBS-subsidised initial therapy with this drug and has received a written authority approval, AND
- Patient must demonstrate a clinically meaningful response to the initial treatment, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use. Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:
- Patient's quality of life including but not limited to level of independence and happiness;
- Patient's cognitive function including but not limited to memory, recognition and interest in environment;
- Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**galantamine 16 mg modified release capsule, 28**
2537M

**galantamine 24 mg modified release capsule, 28**
2531F

**galantamine 8 mg modified release capsule, 28**
2463P

**GALANTAMINE**

**Authority required**
Mild to moderately severe Alzheimer disease

**Treatment Phase: Initial 1**

**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.

Up to a maximum of 2 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. This 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 with this drug with this strength.
**RIVASTIGMINE**

**Authority required (STREAMLINED)**

10108

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 has received a written authority approval, 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.

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**Galantamine 16 mg modified release capsule, 28**

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**Galantamine 24 mg modified release capsule, 28**

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**Galantamine 8 mg modified release capsule, 28**

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rivastigmine 1.5 mg capsule, 56
2475G
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rivastigmine 3 mg capsule, 56
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rivastigmine 4.5 mg capsule, 56
2494G
Max Qty Packs  No. of Rpts Premium $  DPMQ $  MRVSN $  Brand Name and Manufacturer
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rivastigmine 6 mg capsule, 56
2526Y
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rivastigmine 9.5 mg/24 hours patch, 30
2551G
Max Qty Packs  No. of Rpts Premium $  DPMQ $  MRVSN $  Brand Name and Manufacturer
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rivastigmine 4.6 mg/24 hours patch, 30
2477J
Max Qty Packs  No. of Rpts Premium $  DPMQ $  MRVSN $  Brand Name and Manufacturer
1  5  ..  81.52  41.00  Exelon Patch 5 [NV]

- RIVASTIGMINE

Authority required
Mild to moderately severe Alzheimer disease
Treatment Phase: Initial 1
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.
Up to a maximum of 2 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. This 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 with this drug with this strength.

Authority required
Mild to moderately severe Alzheimer disease
Treatment Phase: Initial 1
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.
Up to a maximum of 2 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. This 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 with this drug with this strength.
RIVASTIGMINE

Authority required
Mild to moderately severe Alzheimer disease
Treatment Phase: Initial 2

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.

Application through this treatment restriction must be made in writing.

Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month’s therapy and sufficient repeats to complete 6 months’ initial treatment with this strength of this drug will be authorised under this restriction.

Where no prior approval has been issued before this application, 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 2

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 theClinicians 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.
Application through this treatment restriction must be made in writing.
Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month’s therapy and sufficient repeats to complete 6 months’ initial treatment with this strength of this drug will be authorised under this restriction.
Where no prior approval has been issued before this application, up to a maximum of 1 month’s therapy plus 5 repeats will be authorised.

**rivastigmine 13.3 mg/24 hours patch, 30**

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**rivastigmine 1.5 mg capsule, 56**

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**rivastigmine 9.5 mg/24 hours patch, 30**

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**rivastigmine 4.6 mg/24 hours patch, 30**

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**Other anti-dementia drugs**

- **MEMANTINE**

  **Authority required**
  Moderately severe Alzheimer disease
  Treatment Phase: Initial 2
  Clinical criteria:
  - Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14, **AND**
  - The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
  - The treatment must be the sole PBS-subsidised therapy for this condition.
  
  The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.
  Application through this treatment restriction must be made in writing.
  Where a course of PBS-subsidised treatment with this drug with this strength was approved under the Initial 1 restriction, no more than 1 month’s therapy and sufficient repeats to complete 6 months’ initial treatment with this strength of this drug will be authorised under this restriction.
  Where no prior approval has been issued before this application, up to a maximum of 1 month’s therapy plus 5 repeats will be authorised.

  **Authority required**
  Moderately severe Alzheimer disease
  Treatment Phase: Initial 2
  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:
MEMANTINE

Authority required
Moderately severe Alzheimer disease
Treatment Phase: Initial 1
Clinical criteria:
- Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14, AND
- The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.

Up to a maximum of 2 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. This 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 with this strength of this drug will be authorised.

Authority required
Moderately severe Alzheimer disease
Treatment Phase: Initial 1
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.

Up to a maximum of 2 months' initial therapy will be authorised for this drug, for this strength under this treatment restriction. This 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 with this drug with this strength.
MEMANTINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

10104

Moderately severe Alzheimer disease

Clinical criteria:

- Patient must have received six months of sole PBS-subsidised initial therapy with this drug and has received a written authority approval, 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.

OTHER NERVOUS SYSTEM DRUGS

PARASYMPATHOMIMETICS

Anticholinesterases

PYRIDOSTIGMINE

pyridostigmine bromide 10 mg tablet, 50

pyridostigmine bromide 180 mg modified release tablet, 50

pyridostigmine bromide 60 mg tablet, 150

Choline esters

BETHANECHOL

bethanechol chloride 10 mg tablet, 100

DRUGS USED IN ADDICTIVE DISORDERS

Drugs used in nicotine dependence
**NERVOUS SYSTEM**

- **BUPROPION**

  Note Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

  Note The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.

  Note No increase in the maximum quantity or number of units may be authorised.

  Note No increase in the maximum number of repeats may be authorised.

  Authority required (STREAMLINED)

  6881

  Nicotine dependence

  Treatment Phase: Completion of a short-term (9 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 received PBS-subsidised treatment with this drug during this current course of treatment, **AND**
  - Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

  **Treatment criteria:**
  - Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

  bupropion hydrochloride 150 mg modified release tablet, 90

  8710K

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- **BUPROPION**

  Note Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

  Note The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.

  Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

  Note No increase in the maximum quantity or number of units may be authorised.

  Note No increase in the maximum number of repeats may be authorised.

  Authority required (STREAMLINED)

  6882

  Nicotine dependence

  Treatment Phase: Commencement of a short-term (9 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, **AND**
  - Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

  **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 PBS-subsidised treatment is initiated.
  - Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

  bupropion hydrochloride 150 mg modified release tablet, 30

  8465M

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- **NICOTINE**

  Note No increase in the maximum quantity or number of units may be authorised.

  Note No increase in the maximum number of repeats may be authorised.

  Restricted benefit

  Nicotine dependence

  **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, **AND**
  - Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

  **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 PBS-subsidised treatment is initiated.
  - Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.
### NICOTINE

**Note** Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period. Benefit is improved if used in conjunction with a comprehensive support and counselling program.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Restricted benefit

Nicotine dependence

**Population criteria:**
- Patient must be an Aboriginal or a Torres Strait Islander person.

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition.

#### NICOTINE

**Note** Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period. Benefit is improved if used in conjunction with a comprehensive support and counselling program.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Restricted benefit

Nicotine dependence

**Population criteria:**
- Patient must be an Aboriginal or a Torres Strait Islander person.

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period. Benefit is improved if used in conjunction with a comprehensive support and counselling program.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Nicotine 2 mg lozenge, 216</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotinell [ON]</td>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>1161K</td>
<td>1</td>
</tr>
</tbody>
</table>
### NERVOUS SYSTEM

#### General Pharmaceutical Benefits

| nicotine 4 mg lozenge, 216 | 11619M | Max Qty Packs: 1, No. of Rpts: 2, Premium $: 49.90, DPMQ $: 41.00, MRVSN $: 41.00, Brand Name and Manufacturer: Nicotinell [ON] |
| nicotine 2 mg chewing gum, 216 | 11618L | Max Qty Packs: 2, No. of Rpts: 1, Premium $: 68.84, DPMQ $: 41.00, MRVSN $: 41.00, Brand Name and Manufacturer: Nicotinell [ON] |
| nicotine 4 mg chewing gum, 216 | 11612E | Max Qty Packs: 1, No. of Rpts: 2, Premium $: 49.90, DPMQ $: 41.00, MRVSN $: 41.00, Brand Name and Manufacturer: Nicotinell [ON] |

#### VARENICLINE

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

| 6885 | Nicotine dependence |
| 7483 | 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 received PBS-subsidised treatment with 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.

| varenicline 1 mg tablet, 56 | 5469W | Max Qty Packs: 1, No. of Rpts: 2, Premium $: 100.63, DPMQ $: 41.00, MRVSN $: 41.00, Brand Name and Manufacturer: Champix [PF] |

#### VARENICLINE

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)

| 7483 | 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 received PBS-subsidised treatment with 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.

| varenicline 1 mg tablet, 56 | 9129L | Max Qty Packs: 2, No. of Rpts: 1, Premium $: 193.10, DPMQ $: 41.00, MRVSN $: 41.00, Brand Name and Manufacturer: Champix [PF] |

#### VARENICLINE

**Note** A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

**Note** The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months.

**Note** A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

#### Authority required (STREAMLINED)
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, **AND**
- Patient must not receive more than 24 weeks of PBS-subsidised treatment with this drug per 12-month period.

**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 PBS-subsidised treatment is initiated. 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.

**Varenicline 500 microgram tablet [11] (&) varenicline 1 mg tablet [42], 53**

**Max Qty Packs** | **No. of Rpts** | **Premium $** | **DPMQ $** | **MRVSN $** | **Brand Name and Manufacturer**
---|---|---|---|---|---
1 | .. | 87.18 | 41.00 | Champix [PF]

**Drugs used in alcohol dependence**

**ACAMPROSATE**

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

**5366**
Alcohol dependence
Clinical criteria:
- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

**Acamprosate calcium 333 mg enteric tablet, 180**

**Max Qty Packs** | **No. of Rpts** | **Premium $** | **DPMQ $** | **MRVSN $** | **Brand Name and Manufacturer**
---|---|---|---|---|---
1 | 1 | 114.87 | 41.00 | *Acamprosate Mylan [AL]* | *APO-Acamprosate [TX]*
| | | | | *Campro [AF]* |

**NALTREXONE**

Caution Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

**Authority required**
Alcohol dependence
Clinical criteria:
- The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

**Naltrexone hydrochloride 50 mg tablet, 30**

**Max Qty Packs** | **No. of Rpts** | **Premium $** | **DPMQ $** | **MRVSN $** | **Brand Name and Manufacturer**
---|---|---|---|---|---
1 | 1 | 130.40 | 41.00 | *APO-Naltrexone [TX]* | *Naltrexone GH [GQ]*

**OTHER NERVOUS SYSTEM DRUGS**
Other nervous system drugs

**RILUZOLE**

Note Continuing Therapy Only:
- For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required**
Amyotrophic lateral sclerosis
Treatment Phase: Initial treatment
Clinical criteria:
- The condition must be diagnosed by a neurologist, **AND**
- Patient must not have had the disease for more than 5 years, **AND**
- Patient must have at least 60 percent of predicted forced vital capacity within the 2 months before commencing therapy with this drug, **AND**
- Patient must be ambulatory; **OR**
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.
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**

Amyotrophic lateral sclerosis

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be ambulatory; **OR**
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

<table>
<thead>
<tr>
<th>Riluzole 50 mg tablet, 56</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8664B</strong></td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
</tr>
<tr>
<td>* APO-Riluzole [TX]</td>
</tr>
<tr>
<td>* Rilutek [SW]</td>
</tr>
<tr>
<td>* Riluzole Sandoz [SZ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Riluzole 50 mg/10 mL oral liquid, 300 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>11662T</strong></td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
</tr>
<tr>
<td>Teglutik [CS]</td>
</tr>
</tbody>
</table>

**TETRABENAZINE**

**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>Tetrabenazine 25 mg tablet, 112</th>
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<tbody>
<tr>
<td><strong>1330B</strong></td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
</tr>
<tr>
<td>iNova Pharmaceuticals (Australia) Pty Ltd [IL]</td>
</tr>
</tbody>
</table>

**ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS**

**ANTIPROTOZOALS**

**Agents against amoebiasis and other protozoal diseases**

**atoquaione**

**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>Atovaquone 750 mg/5 mL oral liquid, 210 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8300W</strong></td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>€1</td>
</tr>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
</tr>
<tr>
<td>Wellvone [AS]</td>
</tr>
</tbody>
</table>

**ANTIMALARIALS**

**Biguanides**

**Atovaquone + Proguanil**

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Note Shared Care Model:**

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
<thead>
<tr>
<th>Confirmed or suspected Plasmodium falciparum malaria</th>
</tr>
</thead>
</table>
### General

**Population criteria:**
- Patient must be aged 3 years or older.

**Clinical criteria:**
- The treatment must be used where quinine containing regimens are inappropriate.

### atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12

<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>9439T</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Malarone [GK]</td>
</tr>
</tbody>
</table>

### Methanolquinolines

#### QUININE

**Caution** Severe thrombocytopenia has been reported with this drug.

**Authority required (STREAMLINED)**

**5633**

**Malaria**

### quinine sulfate dihydrate 300 mg tablet, 50

<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>1975Y</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Quinate [RW]</td>
</tr>
</tbody>
</table>

### Artemisinin and derivatives, combinations

#### ARTEMETHER + LUMEFANTRINE

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Restricted benefit**
- Confirmed or suspected Plasmodium falciparum malaria

**Clinical criteria:**
- Patient must be unable to swallow a solid dosage form of artemether with lumefantrine.

### artemether 20 mg + lumefantrine 120 mg dispersible tablet, 18

<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>5296R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riamet 20mg/120mg Dispersible [SZ]</td>
</tr>
</tbody>
</table>

### ARTEMETHER + LUMEFANTRINE

**Note** This drug is not PBS-subsidised for prophylaxis of malaria.

**Restricted benefit**
- Confirmed or suspected Plasmodium falciparum malaria

### artemether 20 mg + lumefantrine 120 mg tablet, 24

<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>9498X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Riamet [SZ]</td>
</tr>
</tbody>
</table>

### ANTHELMINTICS

#### ANTITREMATODALS

**Quinoline derivatives and related substances**

#### PRAZIQUANTEL

**Authority required (STREAMLINED)**

**5659**

**Schistosomiasis**

### praziquantel 600 mg tablet, 8

<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>9447F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Biltricide [BN]</td>
</tr>
</tbody>
</table>

### ANTINEMATODAL AGENTS

**Benzimidazole derivatives**

#### ALBENDAZOLE

**Authority required (STREAMLINED)**

**5607**

**Hydatid disease**

**Clinical criteria:**
- The treatment must be in conjunction with surgery; OR
- The treatment must be used when a surgical cure cannot be achieved; OR
- The treatment must be used when surgery cannot be used.
### ALBENDAZOLE

**Authority required (STREAMLINED)**

<table>
<thead>
<tr>
<th>Code</th>
<th>Product Description</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5680</td>
<td>Tapeworm infestation</td>
<td>Eskazole [AS]</td>
</tr>
<tr>
<td>5817</td>
<td>Whipworm infestation</td>
<td>Zentel [AS]</td>
</tr>
</tbody>
</table>

**Population criteria:**
- Patient must be an Aboriginal or a Torres Strait Islander person.

**Strongyloidiasis**

<table>
<thead>
<tr>
<th>Code</th>
<th>Product Description</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5797</td>
<td>Hookworm infestation</td>
<td>Zentel [AS]</td>
</tr>
</tbody>
</table>

### PYRANTEL

**Authority required (STREAMLINED)**

<table>
<thead>
<tr>
<th>Code</th>
<th>Product Description</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3048K</td>
<td>250 mg tablet</td>
<td>Anthel 250 [AF]</td>
</tr>
<tr>
<td>3047J</td>
<td>125 mg tablet</td>
<td>Anthel 125 [AF]</td>
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</table>

### IVERMECTIN

**Authority required (STREAMLINED)**

<table>
<thead>
<tr>
<th>Code</th>
<th>Product Description</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8359Y</td>
<td>3 mg tablet</td>
<td>Stromectol [MK]</td>
</tr>
</tbody>
</table>

**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 be undergoing topical therapy for this condition; OR
- Patient must have a contraindication to topical treatment.
RESPIRATORY SYSTEM

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 3 mg tablet, 4
2868Y
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS

ECTOPARASITICIDES, INCL. SCABICIDES
Pyrethrines, incl. synthetic compounds

PERMETHRIN
permethrin 5% cream, 30 g
3054R
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

RESPIRATORY SYSTEM

NASAL PREPARATIONS
DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE
Other nasal preparations

MUPIROCIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)
6647
Staphylococcus aureus infection

Clinical criteria:
- Patient must have nasal colonisation with the bacteria.

Population criteria:
- Patient must be an Aboriginal or a Torres Strait Islander person.

mupirocin 2% ointment, 3 g
9440W
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

mupirocin 2% ointment, 5 g
11822F
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

ADRENERGICS, INHALANTS
Selective beta-2-adrenoreceptor agonists

FORMOTEROL (EFORMOTEROL)

Restricted benefit
Asthma

Clinical criteria:
- Patient must experience frequent episodes of the condition, AND
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

formoterol (eformoterol) fumarate dihydrate 12 microgram powder for inhalation, 60 capsules
8136F
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 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>1</td>
<td>5</td>
<td>..</td>
<td>33.22</td>
<td>34.51</td>
<td>Oxis Turbuhaler [AP]</td>
</tr>
</tbody>
</table>

formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 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>1</td>
<td>5</td>
<td>..</td>
<td>26.13</td>
<td>27.42</td>
<td>Oxis Turbuhaler [AP]</td>
</tr>
</tbody>
</table>

- **INDACATEROL**

  **Note** This drug is not PBS-subsidised for the treatment of asthma.

  **Note** The treatment must not be used in combination with an ICS/LABA, or LAMA/LABA

  **Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

  **Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

  **Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

- **SALBUTAMOL**

  **Restricted benefit**

  Chronic obstructive pulmonary disease (COPD)

  **Clinical criteria:**

  - Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

  **salbutamol 100 microgram/actuation inhalation, 200 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>2</td>
<td>5</td>
<td>..</td>
<td>21.68</td>
<td>22.97</td>
<td>Asmol CFC-Free with dose counter [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>26.68</td>
<td>22.97</td>
<td>Ventolin CFC-Free with dose counter [GK]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.00</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

  **salbutamol 100 microgram/actuation inhalation, 200 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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<tbody>
<tr>
<td>2</td>
<td>5</td>
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<td>21.69</td>
<td>Asmol CFC-free [AL]</td>
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<td></td>
<td>24.06</td>
<td>21.69</td>
<td>Ventolin CFC-free [GK]</td>
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<tr>
<td></td>
<td></td>
<td>3.66</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

- **SALBUTAMOL**

  **Restricted benefit**

  Bronchospasm

  **Clinical criteria:**

  - Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

  **salbutamol 100 microgram/actuation breath activated inhalation, 200 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>2</td>
<td>5</td>
<td>..</td>
<td>40.00</td>
<td>41.00</td>
<td>Airomir Autohaler [IL]</td>
</tr>
</tbody>
</table>

- **SALBUTAMOL**

  **Restricted benefit**

  Asthma

  **Clinical criteria:**

  - Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

  **Restricted benefit**

  Chronic obstructive pulmonary disease (COPD)

  **Clinical criteria:**

  - Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

  **Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

  **Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.
### RESPIRATORY SYSTEM

#### General

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Name</th>
<th>Brand Name and Manufacturer</th>
<th>Maximum Quantity</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td><strong>SALMETEROL</strong></td>
<td><strong>Restricted benefit</strong></td>
<td><strong>Asthma</strong></td>
<td>Clinical criteria:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Patient must experience frequent episodes of the condition, <strong>AND</strong></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Patient must be currently receiving treatment with oral corticosteroids; <strong>OR</strong></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.</td>
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<tr>
<td><strong>salmeterol 50 microgram/actuation powder for inhalation, 60 actuations</strong></td>
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<tr>
<td><strong>TERBUTALINE</strong></td>
<td><strong>Authority required (STREAMLINED)</strong></td>
<td><strong>Bronchospasm</strong></td>
<td>Clinical criteria:</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Patient must be unable to achieve co-ordinated use of a metered dose inhaler containing a short-acting beta-2 agonist; <strong>OR</strong></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Patient must have developed a clinically important product-related adverse event during treatment with another short-acting beta-2 agonist.</td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td>Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.</td>
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</tr>
<tr>
<td><strong>terbutaline sulfate 500 microgram/actuation powder for inhalation, 100 actuations</strong></td>
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<td></td>
</tr>
<tr>
<td><strong>BECLOMETASONE + FORMOTEROL (EFORMOTEROL)</strong></td>
<td><strong>Note</strong></td>
<td>This product is not indicated for the initiation of treatment in asthma</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).</td>
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<tr>
<td></td>
<td></td>
<td>The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)</td>
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<td></td>
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<tr>
<td></td>
<td></td>
<td>A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before &quot;stepping up&quot; a patient’s medication regimen.</td>
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<tr>
<td></td>
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<td>This product is not PBS-subsidised for use as ‘maintenance and reliever’ therapy.</td>
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<tr>
<td></td>
<td></td>
<td>This product is not PBS-subsidised for use as ‘anti-inflammatory reliever’ therapy for mild asthma.</td>
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<tr>
<td><strong>Authority required (STREAMLINED)</strong></td>
<td><strong>Asthma</strong></td>
<td></td>
<td>Clinical criteria:</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Population criteria:</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Patient must be aged 18 years or older.</td>
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</table>
beclometasone dipropionate 100 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation inhalation, 120 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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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>43.94</td>
<td>41.00</td>
<td>Fostair [EU]</td>
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</table>

**BUDESONIDE + FORMOTEROL (EFORMOTEROL)**

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Authority required (STREAMLINED)**

10482
Mild asthma

**Clinical criteria:**
- Patient must have asthma and require an anti-inflammatory reliever therapy, AND
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

**Population criteria:**
- Patient must be aged 12 years or over.
  Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

budesonide 100 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations

<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>2</td>
<td>2</td>
<td>..</td>
<td>*48.40</td>
<td>41.00</td>
<td>[AP] Symbicort Rapihaler 100/3</td>
</tr>
</tbody>
</table>

**BUDESONIDE + FORMOTEROL (EFORMOTEROL)**

**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 18 years or older.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Authority required (STREAMLINED)**

10464
Mild asthma

**Clinical criteria:**
- Patient must have asthma and require an anti-inflammatory reliever therapy, AND
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).
  Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 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>1</td>
<td>2</td>
<td>..</td>
<td>43.94</td>
<td>41.00</td>
<td>* DuoResp Spiromax [AF]</td>
</tr>
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</table>

**BUDESONIDE + FORMOTEROL (EFORMOTEROL)**

**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 12 years or over.

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD) or for allergen-induced or exercise-induced bronchoconstriction in the absence of asthma.

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Authority required (STREAMLINED)**

10464
Mild asthma

**Clinical criteria:**
- Patient must have asthma and require an anti-inflammatory reliever therapy, AND
- Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).
  Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.

budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 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>1</td>
<td>2</td>
<td>..</td>
<td>43.94</td>
<td>41.00</td>
<td>* Symbicort Turbuhaler 200/6 [AP]</td>
</tr>
</tbody>
</table>
RESPIRATORY SYSTEM

- **BUDESONIDE + FORMOTEROL (EFORMOTEROL)**

  Note This product is not indicated for the initiation of treatment in asthma

  Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

  Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

  Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

  Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

  **Authority required (STREAMLINED)**

  4380  
  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 100 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

  8796Y

<table>
<thead>
<tr>
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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>$1</td>
<td>5</td>
<td></td>
<td>48.60</td>
<td>41.00</td>
<td>Symbicort Turbuhaler 100/6</td>
</tr>
</tbody>
</table>

  **BUDESONIDE + FORMOTEROL (EFORMOTEROL)**

  Note This product is not indicated for the initiation of treatment in asthma

  Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

  Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

  Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

  Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

  **Authority required (STREAMLINED)**

  4397  
  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 100 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations**

  10024N

<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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</thead>
<tbody>
<tr>
<td>2</td>
<td>5</td>
<td></td>
<td>46.78</td>
<td>41.00</td>
<td>Symbicort Rapihaler 50/3</td>
</tr>
</tbody>
</table>

  **budesonide 100 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations**

  10015D

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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<td></td>
<td>48.40</td>
<td>41.00</td>
<td>Symbicort Rapihaler 100/3</td>
</tr>
</tbody>
</table>

  **BUDESONIDE + FORMOTEROL (EFORMOTEROL)**

  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.

  Note This product is not indicated for the initiation of treatment in asthma

  Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

  Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

  Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

  **Authority required (STREAMLINED)**

  10538  
  Asthma

  **Clinical criteria:**
• Patient must have failed PBS-subsidised fluticasone propionate and salmeterol as a fixed dose combination for this condition.

**Treatment criteria:**
• Must be treated by a respiratory physician; OR
• Must be treated by a paediatrician.

**budesonide 200 microgram/actuation + formoterol (efomoterol) fumarate dihydrate 6 microgram/actuation inhalation, 120 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>12082X</td>
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<td>..</td>
<td>*71.96</td>
<td>Symbicort Rapihaler 200/6</td>
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</tbody>
</table>

**BUDESONIDE + FORMOTEROL (EFOMOTEROL)**

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.

**Authority required (STREAMLINED)**

**Asthma**

**Clinical criteria:**
• Patient must have failed PBS-subsidised fluticasone propionate and salmeterol as a fixed dose combination for this condition.

**Treatment criteria:**
• Must be treated by a respiratory physician; OR
• Must be treated by a paediatrician.

**budesonide 100 microgram/actuation + formoterol (efomoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

<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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**budesonide 200 microgram/actuation + formoterol (efomoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

<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>43.94</td>
<td>*Symbicort Turbuhaler 200/6[AP]</td>
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</tbody>
</table>

**budesonide 50 microgram/actuation + formoterol (efomoterol) fumarate dihydrate 3 microgram/actuation inhalation, 120 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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<tbody>
<tr>
<td>12100W</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*46.78</td>
<td>Symbicort Rapihaler 50/3 [AP]</td>
</tr>
</tbody>
</table>

**budesonide 100 microgram/actuation + formoterol (efomoterol) fumarate dihydrate 3 microgram/actuation inhalation, 120 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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<td>..</td>
<td>*48.40</td>
<td>Symbicort Rapihaler 100/3</td>
</tr>
</tbody>
</table>

**BUDESONIDE + FORMOTEROL (EFOMOTEROL)**

**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Note** Patient must be aged 18 years or older.

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.

**Authority required (STREAMLINED)**

**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
RESPIRATORY SYSTEM

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.

**Budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

<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>
</table>

**BUDESONIDE + FORMOTEROL (EFORMOTEROL)**

Note: Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

Note: Patient must be aged 12 years or over.
Note: This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).
Note: The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)
Note: A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
Note: Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

7970
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.

**Budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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</tbody>
</table>

**BUDESONIDE + FORMOTEROL (EFORMOTEROL)**

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.

Note: This product is not indicated for the initiation of treatment in asthma
Note: The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.
Note: Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations

<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>Symbicort Rapihaler 200/6</td>
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**BUDESONIDE + FORMOTEROL (EFORMOTEROL)**

*Note* Pharmaceutical benefits that have the brand DuoResp Spiromax 400/12 powder for inhalation, 2 x 60 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 400/12 powder for inhalation, 2 x 60 actuations are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**7979**

**Asthma**

**Clinical criteria:**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

*Note* Patient must be aged 18 years or older.

*Note* Symbicort 400/12 is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

*Note* This product is not indicated for the initiation of treatment in asthma

*Note* The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

*Note* A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

*Note* Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient’s medication regimen.

**Authority required (STREAMLINED)**

**10121**

**Chronic obstructive pulmonary disease (COPD)**

**Clinical criteria:**

- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

*Note* This product is not indicated for the initiation of bronchodilatory therapy in COPD.

*Note* The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

*Note* A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

*Note* Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations

<table>
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**FLUTICASONE FUROATE + VILANTEROL**

*Note* This drug is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

*Note* This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

*Note* This product is not indicated for the initiation of treatment in asthma

*Note* The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

*Note* A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

*Note* Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient’s medication regimen.

**Authority required (STREAMLINED)**

**4731**

**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.
RESPIRATORY SYSTEM

fluticasone furoate 200 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

11129R

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**FLUTICASONE FUROATE + VILANTEROL**

Authority required (STREAMLINED)

4711

Asthma

Clinical criteria:
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:
- Patient must be aged 12 years or over.

Note This drug is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

Note This product is not indicated for the initiation of treatment in asthma.

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.

fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

11124L

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**FLUTICASONE PROPIONATE + FORMOTEROL (EFORMOTEROL)**

Note Flutiform is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

Note Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.

Note The product is not indicated for the initiation of treatment in asthma.

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA).

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.

fluticasone propionate 50 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations

2827T

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fluticasone propionate 125 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations

10007Q

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RESPIRATORY SYSTEM

### FLUTICASONE PROPIONATE + SALMETEROL

#### Authority required (STREAMLINED)

4930
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.

#### General Pharmaceutical Benefits

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<th>fluticasone propionate 250 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 10 microgram/actuation inhalation, 120 actuations</th>
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<td>10008R</td>
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#### FLUTICASONE PROPIONATE + SALMETEROL

**Note** This product is not indicated for the initiation of treatment in asthma

**Note** This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

**Note** The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

**Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.

#### Authority required (STREAMLINED)

4930
Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**
- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, AND
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

**Note** The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.
Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

### fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations

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### fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

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</table>

### Adrenergics in combination with anticholinergics incl. triple combinations with corticosteroids

#### Aclidinium + Formoterol (Eformoterol)

- **Note** This product is not PBS-subsidised for the treatment of asthma.
- **Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.
- **Note** The treatment must not be used in combination with an ICS/LABA, LABA, or SAMA
- **Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
- **Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
- **Note** A SAMA includes ipratropium
- **Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
- **Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Authority required (STREAMLINED)**

7798

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

#### Fluticasone Furoate + Umeclidinium + Vilanterol

- **Note** Continuing Therapy Only:
  - For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
  - **Note** Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at http://copdx.org.au/); the assessment and adherence to correct technique should be documented in the patient's medical records.
  - **Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
  - **Note** This product is not PBS-subsidised for the treatment of asthma or the initiation of bronchodilator therapy in COPD.
  - **Note** The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.
  - **Note** A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
  - **Note** A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
  - **Note** An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

**Authority required (STREAMLINED)**

10167

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.
INDACATEROL + GLYCOPPYRNONIUM

Note This product is not PBS-subsidised for the treatment of asthma.
Note This product is not indicated for the initiation of bronchodilator therapy in COPD.
Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA
Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
Note A SAMA includes ipratropium.
Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.

Tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 60 actuations

Note This product is not PBS-subsidised for the treatment of asthma.
Note This product is not indicated for the initiation of bronchodilator therapy in COPD.
Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA
Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
Note A SAMA includes ipratropium.
Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.

Authority required (STREAMLINED)

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

UMECLIDINIUM + VILANTEROL

Note This product is not PBS-subsidised for the treatment of asthma.
Note This product is not indicated for the initiation of bronchodilator therapy in COPD.
Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA
Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.
Note A SAMA includes ipratropium.
Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.

Authority required (STREAMLINED)
Chronic obstructive pulmonary disease (COPD)

Clinical criteria:
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

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OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS

Glucocorticoids

**BECLOMETASONE**

beclometasone dipropionate 50 microgram/actuation inhalation, 200 actuations

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beclometasone dipropionate 100 microgram/actuation inhalation, 200 actuations

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**BECLOMETASONE**

Restricted benefit

Asthma

Clinical criteria:
- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

beclometasone dipropionate 100 microgram/actuation breath activated inhalation, 200 actuations

<table>
<thead>
<tr>
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beclometasone dipropionate 50 microgram/actuation breath activated inhalation, 200 actuations

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**BUDESONIDE**

budesonide 100 microgram/actuation powder for inhalation, 200 actuations

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budesonide 200 microgram/actuation powder for inhalation, 200 actuations

<table>
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budesonide 400 microgram/actuation powder for inhalation, 200 actuations

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**BUDESONIDE**

Authority required (STREAMLINED)

Severe chronic asthma

Clinical criteria:
- Patient must require long-term steroid therapy, AND
- Patient must not be able to use other forms of inhaled steroid therapy.

budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules

<table>
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</table>
budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules

<table>
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<th>DPMQ $</th>
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## CICLESONIDE

### ciclesonide 160 microgram/actuation inhalation, 120 actuations

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### ciclesonide 80 microgram/actuation inhalation, 120 actuations

<table>
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<td>†1</td>
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## FLUTICASONE FUROATE

### fluticasone furoate 100 microgram/actuation powder for inhalation, 30 actuations

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<tbody>
<tr>
<td>†1</td>
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<td>30.14</td>
<td>Amruity Ellipta [GK]</td>
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### fluticasone furoate 200 microgram/actuation powder for inhalation, 30 actuations

<table>
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## FLUTICASONE PROPIONATE

### fluticasone propionate 100 microgram/actuation powder for inhalation, 60 actuations

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### fluticasone propionate 250 microgram/actuation powder for inhalation, 60 actuations

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### fluticasone propionate 500 microgram/actuation powder for inhalation, 60 actuations

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<tr>
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<td></td>
<td></td>
<td></td>
<td>* Fluticasone Cipla Inhaler [LR]</td>
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<tr>
<td></td>
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<td>31.85</td>
<td>30.14</td>
<td>* Flixotide [GK]</td>
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### fluticasone propionate 250 microgram/actuation inhalation, 120 actuations

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<td>41.00</td>
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<td></td>
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<td>* Flixotide [GK]</td>
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### fluticasone propionate 50 microgram/actuation inhalation, 120 actuations

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<td>20.72</td>
<td>Flixotide Junior [GK]</td>
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## Anticholinergics

### Aclidinium

Note The treatment must not be used in combination with a LAMA/LABA or SAMA
Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.
Note A SAMA includes ipratropium.
Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.

Restricted benefit Chronic obstructive pulmonary disease (COPD)

### aclidinium 322 microgram/actuation inhalation: powder for, 60 actuations

<table>
<thead>
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<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>60.35</td>
<td>41.00</td>
<td>Bretarhis Genuair [FK]</td>
</tr>
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</table>
RESPIRATORY SYSTEM

- **GLYCOPPYRONIUM**

  **Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

  **Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

  **Note** A SAMA includes ipratropium

  **Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

  **Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.

  **Restricted benefit**

  Chronic obstructive pulmonary disease (COPD)

  **glycopyrronium 50 microgram powder for inhalation, 30 capsules**

<table>
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<tr>
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<td>41.00</td>
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</table>

- **IPRATROPIUM**

  **Restricted benefit**

  Asthma

  **Clinical criteria:**
  - Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

  **Restricted benefit**

  Chronic obstructive pulmonary disease (COPD)

  **Clinical criteria:**
  - Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

  **Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

  **Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.

  **ipratropium bromide monohydrate 21 microgram/actuation inhalation, 200 actuations**

<table>
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<tr>
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- **IPRATROPIUM**

  **Restricted benefit**

  Asthma

  **Clinical criteria:**
  - Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

  **Restricted benefit**

  Chronic obstructive pulmonary disease (COPD)

  **Clinical criteria:**
  - Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

  **Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

  **Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.

  **ipratropium bromide 250 microgram/mL inhalation solution, 30 x 1 mL ampoules**

<table>
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<td>* Atrvent Adult [BY]</td>
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<tr>
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<td>..</td>
<td>*31.20</td>
<td>32.49</td>
<td>* Atrvent Adult [BY]</td>
</tr>
</tbody>
</table>

- **TIOTROPIUM**

  **Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.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 (1800 645 130).

  **Restricted benefit**

  Severe asthma

  **Clinical criteria:**
  - Patient must have experienced at least one severe exacerbation, which has required documented use of systemic corticosteroids, in the previous 12 months while receiving optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, AND
  - The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.
  - Patient must be aged 18 years or older.
  - Optimal asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

  **tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations**

<table>
<thead>
<tr>
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<th>Premium $</th>
<th>DPMQ $</th>
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<td>..</td>
<td>43.01</td>
<td>41.00</td>
<td>Spiriva Respimat [BY]</td>
</tr>
</tbody>
</table>
### Tiotropium

**Note** Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper 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 (1800 645 130).

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.

#### Authority required (STREAMLINED)

**8606**
Severe asthma

**Treatment criteria:**
- Must be treated by a respiratory physician, paediatric respiratory physician, clinical immunologist, allergist, paediatrician or general physician experienced in the management of patients with severe asthma; or in consultation with one of these specialists.

**Clinical criteria:**
- 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 have experienced at least one severe exacerbation prior to receiving PBS-subsidised treatment with this drug for this condition, which has required documented use of systemic corticosteroids in the previous 12 months while receiving optimised asthma therapy; **OR**
- Patient must have experienced frequent episodes of moderate asthma exacerbations prior to receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

**Population criteria:**
- Patient must be aged 6 to 17 years inclusive.

Optimised asthma therapy includes adherence to the maintenance combination of a medium to high dose ICS and a LABA. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative.

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**tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations**

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<tr>
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<th>Packs</th>
<th>No. of Rpts</th>
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<td>41.00</td>
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<td>Spiriva Respimat [BY]</td>
</tr>
</tbody>
</table>

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**Tiotropium**

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.

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**Restricted benefit**
Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease

**Treatment Phase: Long-term maintenance treatment**

**tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations**

<table>
<thead>
<tr>
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<th>Packs</th>
<th>No. of Rpts</th>
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<td>Spiriva Respimat [BY]</td>
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**Tiotropium**

**Note** Pharmaceutical benefits that have the form tiotropium 18 microgram powder for inhalation and pharmaceutical benefits that have the form tiotropium 13 microgram powder for inhalation are equivalent for the purposes of substitution.

**Note** The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note** A SAMA includes ipratropium.

**Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

**Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before “stepping up” a patient’s medication regimen.

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**Restricted benefit**
Chronic obstructive pulmonary disease (COPD)
tiotropium 18 microgram powder for inhalation, 30 capsules

8626B

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tiotropium 13 microgram powder for inhalation, 30 capsules

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<td>43.01</td>
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</tr>
</tbody>
</table>

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**UMECLIDINIUM**

- **Note** The treatment must not be used in combination with a LAMA/LABA or SAMA
- **Note** A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.
- **Note** A SAMA includes ipratropium
- **Note** Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.
- **Note** Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

**Note**
The treatment must not be used in combination with a LAMA/LABA or SAMA

**Note**
A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

**Note**
A SAMA includes ipratropium

**Note**
Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

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umeclidinium 62.5 microgram/actuation inhalation: powder for, 30 actuations

10187E

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<tr>
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**Antiallergic agents, excl. corticosteroids**

**CROMOGLYCATE**

sodium cromoglycate 5 mg/actuation inhalation, 112 actuations

8334P

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sodium cromoglycate 1 mg/actuation inhalation, 200 actuations

8767K

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**NEDOCROMIL**

nedocromil sodium 2 mg/actuation inhalation, 112 actuations

8365G

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**ADRENERGICS FOR SYSTEMIC USE**

**Alpha- and beta-adrenoreceptor agonists**

**ADRENALINE (EPINEPHRINE)**

adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

1016L

<table>
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<tr>
<th>Max.Qty Packs</th>
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<td>21.68</td>
<td>22.97</td>
<td>Link Medical Products Pty Ltd [LM]</td>
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</tbody>
</table>

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adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

5004J

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<th>DPMO $</th>
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<td>21.68</td>
<td>22.97</td>
<td>Link Medical Products Pty Ltd [LM]</td>
</tr>
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**ADRENALINE (EPINEPHRINE)**

- **Note** The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)
- **Note** Authority approvals will be limited to a maximum quantity of 2 auto-injectors at any one time.
- **Note** No applications for repeats will be authorised.

**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 (epinephrine) 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.

### Adrenaline (epinephrine) 150 microgram/0.3 mL injection, 0.3 mL pen device

<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>8697R</td>
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### Adrenaline (epinephrine) 300 microgram/0.3 mL injection, 0.3 mL pen device

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**Selective beta-2-adrenoreceptor agonists**

### Salbutamol

Salbutamol 2 mg/5 mL oral liquid, 150 mL

<table>
<thead>
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### Terbutaline

Terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules

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**Other systemic drugs for obstructive airway diseases**

**Xanthines**

### Theophylline

**Caution** Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring.

**Note** Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
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**Leukotriene receptor antagonists**

### Montelukast

**Note** This drug 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.
Note This drug is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for this drug will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to this drug.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

Asthma

Treatment Phase: First-line prevention

Population criteria:
- Patient must be aged 2 to 5 years inclusive.

Clinical criteria:
- The condition must be frequent intermittent; OR
- The condition must be mild persistent, AND
- The treatment must be the single preventer agent, AND
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

Note This drug 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.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

Asthma

Treatment Phase: Prevention of condition

Clinical criteria:
- The condition must be exercise-induced, AND
- The treatment must be as an alternative to adding salmeterol xinafoate; OR
- The treatment must be an alternative to adding formoterol fumarate, AND
- The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid, AND
- Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms.

Population criteria:
- Patient must be aged 6 to 14 years inclusive.

Note This drug is not PBS-subsidised for use in a patient aged 6 to 14 years for use in combination with other preventer medications. PBS subsidy for this drug will therefore cease for a child aged 6 to 14 years who requires a preventer medication in addition to this drug.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.
### SENSORY ORGANS

#### ANTIHISTAMINES FOR SYSTEMIC USE

**Phenothiazine derivatives**

#### PROMETHAZINE

promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules

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#### SENSORY ORGANS

#### OPHTHALMOLOGICALS

#### ANTIINFECTIVES

**Antibiotics**

#### AZITHROMYCIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Trachoma

azithromycin 200 mg/5 mL powder for oral liquid, 15 mL

<table>
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azithromycin 500 mg tablet, 2

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#### CHLORAMPHENICOL

**Restricted benefit**

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

chloramphenicol 0.5% eye drops, 10 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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#### GENTAMICIN

**Restricted benefit**

Perioperative use in ophthalmic surgery

**Restricted benefit**

Suspected Pseudomonal eye infection

gentamicin 0.3% 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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#### GENTAMICIN

**Restricted benefit**

Invasive ocular infection

**Restricted benefit**

Perioperative use in ophthalmic surgery

**Restricted benefit**

Suspected Pseudomonal eye infection

gentamicin 0.3% eye drops, 5 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>2</td>
<td>22.34</td>
<td>23.63</td>
<td>Genoptic [AG]</td>
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</tbody>
</table>

#### TOBRAMYCIN

**Restricted benefit**

Perioperative use in ophthalmic surgery

**Restricted benefit**

Suspected Pseudomonal eye infection
tobramycin 0.3% eye drops, 5 mL
5569D

- **Max.Qty Packs**
  - 1
- **No. of Rpts**
  - 2
- **Premium $**
  - 22.64
- **DPMQ $**
  - 23.93
- **MRVSN $**
  - Brand Name and Manufacturer
  - Tobrex [NV]

### TOBRAMYCIN

**Restricted benefit**
Invasive ocular infection

**Restricted benefit**
Perioperative use in ophthalmic surgery

**Restricted benefit**
Suspected Pseudomonal eye infection

tobramycin 0.3% eye ointment, 3.5 g
5570E

- **Max.Qty Packs**
  - 1
- **No. of Rpts**
  - ..
- **Premium $**
  - 25.20
- **DPMQ $**
  - 26.49
- **MRVSN $**
  - Brand Name and Manufacturer
  - Tobrex [NV]

### Antivirals

#### ACICLOVIR

**Restricted benefit**
Herpes simplex keratitis

aciclovir 3% eye ointment, 4.5 g
11654J

- **Max.Qty Packs**
  - 1
- **No. of Rpts**
  - ..
- **Premium $**
  - 65.24
- **DPMQ $**
  - 41.00
- **MRVSN $**
  - Brand Name and Manufacturer
  - AciVision [DZ]

#### ACICLOVIR

**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.


### 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
1217C

- **Max.Qty Packs**
  - 2
- **No. of Rpts**
  - ..
- **Premium $**
  - 31.20
- **DPMQ $**
  - 32.49
- **MRVSN $**
  - Brand Name and Manufacturer
  - CiloQuin [NM]

#### 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
5564W

- **Max.Qty Packs**
  - 2
- **No. of Rpts**
  - ..
- **Premium $**
  - 31.20
- **DPMQ $**
  - 32.49
- **MRVSN $**
  - Brand Name and Manufacturer
  - CiloQuin [NM]
**SENSORY ORGANS**

- **OFLOXACIN**
  - **Authority required**
  - Bacterial keratitis
  - **Treatment criteria:**
    - Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

  **ofloxacin 0.3% eye drops, 5 mL**
  - Max Qty Packs: 5567B
  - Max Qty Packs: 8383F
  - 2 packs
  - Premium $: 32.42
  - MRVSN $: 33.71
  - Ocufox [AG]

- **OFLOXACIN**
  - **Authority required**
  - Bacterial keratitis
  - **Treatment criteria:**
    - Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

  **ofloxacin 0.3% eye drops, 5 mL**
  - Max Qty Packs: 5567B
  - Max Qty Packs: 8383F
  - 2 packs
  - Premium $: 32.42
  - MRVSN $: 33.71
  - Ocufox [AG]

- **ANTIINFLAMMATORY AGENTS**
  - **Corticosteroids, plain**

  - **DEXAMETHASONE**
    - **dexamethasone 0.1% eye drops, 5 mL**
      - Max Qty Packs: 1288T
      - 1 pack
      - Premium $: 15.66
      - DPMO: 16.95
      - Maxidex [NV]

  - **DEXAMETHASONE**
    - **dexamethasone 700 microgram implant, 1**
      - Max Qty Packs: 11317P
      - 1 pack
      - Premium $: 1376.59
      - MRVSN: 41.00
      - Ozurdex [AG]

  - **DEXAMETHASONE**
    - **dexamethasone 0.1% eye drops, 5 mL**
      - Max Qty Packs: 5565X
      - 1 pack
      - Premium $: 15.66
      - DPMO: 16.95
      - Maxidex [NV]

  - **DEXAMETHASONE**
    - **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 for applications for treatment of one eye.
      - Where both eyes are affected by the condition, a quantity of 2 units can be requested on the same authority prescription form.

  - **Authority required**
    - Diabetic macular oedema (DMO)
    - Treatment Phase: Initial treatment
    - **Treatment criteria:**
      - Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.
    - **Clinical criteria:**
      - Patient must have visual impairment due to diabetic macular oedema, **AND**
Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, AND

The condition must be diagnosed by optical coherence tomography; OR

The condition must be diagnosed by fluorescein angiography, AND

Patient must have had a cataract removed in the treated eye; OR

Patient must be scheduled for cataract surgery in the treated eye, AND

Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR

Patient must be unsuitable for treatment with VEGF inhibitors; OR

Patient must have failed prior treatment with VEGF inhibitors, AND

The treatment must be as monotherapy; OR

The treatment must be in combination with laser photocoagulation, AND

The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made in writing.

A written application must include:

a) a completed authority prescription form;
b) a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
c) a copy of the optical coherence tomography or fluorescein angiogram report.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye, AND
- Patient must have previously been issued with an authority prescription for this drug for the same eye, AND
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**dexamethasone 700 microgram implant, 1**

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<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>1376.59</td>
<td>41.00</td>
<td>Ozurdex [AG]</td>
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</table>

**DEXAMETHASONE**

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

Note Where both eyes are affected by the condition, a quantity of 2 units can be requested on the same authority prescription form.

**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), AND
• Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, AND
• The condition must be diagnosed by optical coherence tomography; OR
• The condition must be diagnosed by fluorescein angiography, AND
• Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
• Patient must have failed prior treatment with VEGF inhibitors, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.
Authority approval for initial treatment of each eye must be sought.
The first authority application for each eye must be made in writing.
A written application must include:
a) a completed authority prescription form;
b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
c) a copy of the optical coherence tomography or fluorescein angiogram report.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Branch retinal vein occlusion with macular oedema
Treatment Phase: Continuing treatment
Treatment criteria:
• Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.
Clinical criteria:
• Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Central retinal vein occlusion with macular oedema
Treatment Phase: Initial treatment
Treatment criteria:
• Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.
Clinical criteria:
• Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), AND
• Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, AND
• The condition must be diagnosed by optical coherence tomography; OR
• The condition must be diagnosed by fluorescein angiography, AND
• Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; OR
• Patient must have failed prior treatment with VEGF inhibitors, AND
• The treatment must be the sole PBS-subsidised therapy for this condition.
Authority approval for initial treatment of each eye must be sought.
The first authority application for each eye must be made in writing.
A written application must include:
a) a completed authority prescription form;
b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
c) a copy of the optical coherence tomography or fluorescein angiogram report.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Authority required
Central retinal vein occlusion with macular oedema
Treatment Phase: Continuing treatment

Treatment criteria:
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Note: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

dexamethasone 700 microgram implant, 1

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### FLUOROMETHOLONE

fluorometholone 0.1% eye drops, 5 mL

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Note: No applications for increased maximum quantities will be authorised.
Note: No applications for increased repeats will be authorised.

fluorometholone 0.1% eye drops, 5 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>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>$1</td>
<td></td>
<td>14.98</td>
<td>16.27</td>
<td></td>
<td>FML Liquifilm [AG]</td>
</tr>
</tbody>
</table>

### 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>
</tr>
</thead>
<tbody>
<tr>
<td>$1</td>
<td></td>
<td>14.98</td>
<td>16.27</td>
<td></td>
<td>Flarex [NV]</td>
</tr>
</tbody>
</table>

Note: No applications for increased maximum quantities will be authorised.
Note: No applications for increased repeats will be authorised.

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>
</tr>
</thead>
<tbody>
<tr>
<td>$1</td>
<td></td>
<td>14.98</td>
<td>16.27</td>
<td></td>
<td>Flarex [NV]</td>
</tr>
</tbody>
</table>

### 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>
</tr>
</thead>
<tbody>
<tr>
<td>$1</td>
<td></td>
<td>17.47</td>
<td>18.76</td>
<td></td>
<td>Hycor [AS]</td>
</tr>
</tbody>
</table>

### HYDROCORTISONE ACETATE

Note: No applications for increased maximum quantities will be authorised.
Note: No applications for increased repeats will be authorised.

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>
</tr>
</thead>
<tbody>
<tr>
<td>$1</td>
<td></td>
<td>17.47</td>
<td>18.76</td>
<td></td>
<td>Hycor [AS]</td>
</tr>
</tbody>
</table>

Corticosteroids and mydriatics in combination

### PREDNISOLONE ACETATE + PHENYLEPHRINE

Restricted benefit
Severe eye inflammation

Clinical criteria:
- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.
Population criteria:
- Patient must identify as Aboriginal or Torres Strait Islander.

**Prednisolone acetate 1% + phenylephrine hydrochloride 0.12% 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>
</tr>
</thead>
<tbody>
<tr>
<td>11908R</td>
<td>..</td>
<td>..</td>
<td>28.89</td>
<td>30.18</td>
<td>Prednefrin Forte [AG]</td>
</tr>
</tbody>
</table>

- **PREDNISOLONE ACETATE + PHENYLEPHRINE**
  - **Restricted benefit**
  - Corneal grafts
  - **Restricted benefit**
  - Uveitis

**Prednisolone acetate 1% + phenylephrine hydrochloride 0.12% 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>
</tr>
</thead>
<tbody>
<tr>
<td>3112T</td>
<td>..</td>
<td>..</td>
<td>28.89</td>
<td>30.18</td>
<td>Prednefrin Forte [AG]</td>
</tr>
</tbody>
</table>

- **PREDNISOLONE ACETATE + PHENYLEPHRINE**
  - **Note**: No increase in the maximum quantity or number of units may be authorised.
  - **Note**: No increase in the maximum number of repeats may be authorised.

**Uveitis**

**Prednisolone acetate 1% + phenylephrine hydrochloride 0.12% 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>
</tr>
</thead>
<tbody>
<tr>
<td>..</td>
<td>..</td>
<td>..</td>
<td>28.89</td>
<td>30.18</td>
<td>Prednefrin Forte [AG]</td>
</tr>
</tbody>
</table>

---

**ANTIGLAUCOMA PREPARATIONS AND MIOTICS**

**Sympathomimetics in glaucoma therapy**

- **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>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>8083K</td>
<td>..</td>
<td>..</td>
<td>37.08</td>
<td>38.37</td>
<td>Iopidine 0.5% [NV]</td>
</tr>
</tbody>
</table>

- **BRIMONIDINE**

**Brimonidine tartrate 0.15% 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>5298W</td>
<td>5</td>
<td>..</td>
<td>23.95</td>
<td>25.24</td>
<td>Alphagan P 1.5 [AG]</td>
</tr>
</tbody>
</table>

**Brimonidine tartrate 0.2% 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>8351M</td>
<td>5</td>
<td>..</td>
<td>23.95</td>
<td>25.24</td>
<td>* Enidin [PE]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>25.37</td>
<td>25.24</td>
<td>* Alphagan [AG]</td>
</tr>
</tbody>
</table>

- **BRIMONIDINE + TIMOLOL**
  - ** Restricted benefit**
  - Elevated intra-ocular pressure

**Clinical criteria:**
- The condition must have been inadequately controlled with monotherapy, **AND**
## Sensory Organs

- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

### Brimonidine Tartrate 0.2% + Timolol 0.5% Eye Drops, 5 mL

<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>Combigan [AG]</td>
<td>1</td>
<td>5</td>
<td>29.07</td>
<td>30.36</td>
<td></td>
</tr>
</tbody>
</table>

**Note:** For prescribing in accordance with Optometry Board of Australia guidelines.

### Carbonic Anhydrase Inhibitors

#### Acetzolamide

- **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>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>Diamox [RW]</td>
<td>1</td>
<td>3</td>
<td>25.55</td>
<td>26.84</td>
<td></td>
</tr>
</tbody>
</table>

### BRINZOLAMIDE

- **Note:** continuing therapy only.

<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>Azopt [NV]</td>
<td>1</td>
<td>3</td>
<td>26.24</td>
<td>27.53</td>
<td></td>
</tr>
</tbody>
</table>

---

**General**

- **Sensory Organs**

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**Schedule of Pharmaceutical Benefits – December 2020**

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**916**
### BRINZOLAMIDE

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**brinzolamide 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>
</tr>
</thead>
<tbody>
<tr>
<td>$1</td>
<td>5</td>
<td>..</td>
<td>26.24</td>
<td>27.53</td>
<td>* BrinzoQuin [NM]</td>
</tr>
</tbody>
</table>

**BRINZOLAMIDE + BRIMONIDINE**

**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% + brimonidine tartrate 0.2% 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>$1</td>
<td>5</td>
<td>..</td>
<td>28.58</td>
<td>29.87</td>
<td>* Simbrinza 1%/0.2% [NV]</td>
</tr>
</tbody>
</table>

**BRINZOLAMIDE + BRIMONIDINE**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**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>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>29.81</td>
<td>31.10</td>
<td>* Azarga [NV]</td>
</tr>
</tbody>
</table>

**BRINZOLAMIDE + TIMOLOL**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

**DORZOLAMIDE**

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.
## Sensory Organs

**DORZOLAMIDE + TIMOLOL**

**Restricted benefit**
Elevated intraocular 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% 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>5541P‡</td>
<td>1</td>
<td>..</td>
<td>19.87</td>
<td>21.16</td>
<td>* APO-Dorzolamide [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Trusamide [AF]</td>
</tr>
</tbody>
</table>

### DORZOLAMIDE + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

**Restricted benefit**
Elevated intraocular 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>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8567X‡</td>
<td>1</td>
<td>..</td>
<td>22.61</td>
<td>23.90</td>
<td>* APO-Dorzolamide/Timolol 20/5 [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Cosdor [AF]</td>
</tr>
</tbody>
</table>

### Beta Blocking Agents

**BETAXOLOL**

### Betaxolol 0.5% 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>2825Q‡</td>
<td>1</td>
<td>..</td>
<td>19.28</td>
<td>20.57</td>
<td>* BetoQuin [NM]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Betoptic [NV]</td>
</tr>
</tbody>
</table>

### BETAXOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

### TIMOLOL

#### 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>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1926J‡</td>
<td>1</td>
<td>..</td>
<td>17.80</td>
<td>19.09</td>
<td>Timoptol XE [MF]</td>
</tr>
</tbody>
</table>

#### Timolol 0.5% 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>1279H‡</td>
<td>1</td>
<td>..</td>
<td>17.74</td>
<td>19.03</td>
<td>Timoptol [MF]</td>
</tr>
</tbody>
</table>

### TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

#### 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>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5550D‡</td>
<td>1</td>
<td>..</td>
<td>17.80</td>
<td>19.09</td>
<td>Timoptol XE [MF]</td>
</tr>
</tbody>
</table>

#### Timolol 0.5% 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>5548B‡</td>
<td>1</td>
<td>..</td>
<td>17.74</td>
<td>19.03</td>
<td>Timoptol [MF]</td>
</tr>
<tr>
<td>Prostaglandin analogues1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### BIMATOPROST

#### bimatoprost 0.03% eye drops, 3 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>‡1</td>
<td>5</td>
<td>..</td>
<td>36.94</td>
<td>38.23</td>
<td>* APO-Bimatoprost [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Bimatoprost Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Bimatoprost [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Lumigan [AG]</td>
</tr>
</tbody>
</table>

### BIMATOPROST

#### bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses

<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>‡1</td>
<td>5</td>
<td>..</td>
<td>32.94</td>
<td>34.23</td>
<td>Lumigan PF [AG]</td>
</tr>
</tbody>
</table>

### BIMATOPROST

#### bimatoprost 0.03% eye drops, 3 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>‡1</td>
<td>5</td>
<td>..</td>
<td>36.94</td>
<td>38.23</td>
<td>* APO-Bimatoprost [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Bimatoprost Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Bimatoprost [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Lumigan [AG]</td>
</tr>
</tbody>
</table>

### BIMATOPROST + TIMOLOL

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, AND
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

#### bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses

<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>‡1</td>
<td>5</td>
<td>..</td>
<td>37.73</td>
<td>39.02</td>
<td>GANfort PF 0.3/5 [AG]</td>
</tr>
</tbody>
</table>

### BIMATOPROST + TIMOLOL

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

- The condition must have been inadequately controlled with monotherapy, AND
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

#### bimatoprost 0.03% + timolol 0.5% eye drops, 3 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>‡1</td>
<td>5</td>
<td>..</td>
<td>41.39</td>
<td>41.00</td>
<td>Ganfort 0.3/5 [AG]</td>
</tr>
</tbody>
</table>

### BIMATOPROST + TIMOLOL

**Note** For prescribing in accordance with Optometry Board of Australia guidelines.

#### bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
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<th>MRVSN $</th>
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<td>37.73</td>
<td>39.02</td>
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**Note** For prescribing in accordance with Optometry Board of Australia guidelines.
### SENSORY ORGANS

**LATANOPROST**

**latanoprost 0.005% eye drops, 2.5 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<td>* Latanoprost Actavis [EA]</td>
<td>* Xalaprost [AF]</td>
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<td></td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>* Xalatan [UJ]</td>
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</tbody>
</table>

*Note* For prescribing in accordance with Optometry Board of Australia guidelines.

**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>
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**LATANOPROST + TIMOLOL**

*Note* For prescribing in accordance with Optometry Board of Australia guidelines.

**TAFLUPROST**

**tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses**

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**TAFLUPROST**

*Note* For prescribing in accordance with Optometry Board of Australia guidelines.

**TRAVOPROST**

**travoprost 0.004% eye drops, 2.5 mL**

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<thead>
<tr>
<th>Max Qty Packs</th>
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**TRAVOPROST**

*Note* For prescribing in accordance with Optometry Board of Australia guidelines.
travoprost 0.004% eye drops, 2.5 mL

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**TRAVOPROST + 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.

travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL

<table>
<thead>
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**TRAVOPROST + TIMOLOL**

*Note* For prescribing in accordance with Optometry Board of Australia guidelines.

*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.

travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL

<table>
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**MYDRIATICS AND CYCLOPLEGICS**

*Anticholinergics*

**ATROPINE SULFATE**

atropine sulfate monohydrate 1% eye drops, 15 mL

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<tr>
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**OCULAR VASCULAR DISORDER AGENTS**

*Antineovascularisation agents*

**AFLIBERCEPT**

*Note* Special Pricing Arrangements apply.

*Note* No increase in the maximum number of repeats may be authorised.

*Note* No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

*Note* Where both eyes are affected by the condition, a quantity of 2 units can be requested on the same authority prescription form.

*Note* Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

**Authority required**
Diabetic macular oedema (DMO)

**Treatment Phase:** Initial treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**
- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made in writing.
A written application must include:

a) a completed authority prescription form;
b) a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
c) a copy of the optical coherence tomography or fluorescein angiogram report.

**Note**
Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au.
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Diabetic macular oedema (DMO)
Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note**
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### aflibercept 4 mg/0.1 mL injection, 0.1 mL vial
10505X

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### aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe
12153P

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<td>41.00</td>
<td>Eylea [BN]</td>
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</table>

**AFLIBERCEPT**

**Note**
Special Pricing Arrangements apply.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note**
Where both eyes are affected by the condition, a quantity of 2 units can be requested on the same authority prescription form.

**Note**
Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

**Authority required**
Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Initial treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**
- The condition must be due to pathologic myopia (PM), **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.
The first authority application for each eye must be made in writing.
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 optical coherence tomography or fluorescein angiogram report.

**Note**
Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**
- The condition must be due to pathologic myopia (PM), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**AFLIBERCEPT**

- Note Special Pricing Arrangements apply.
- Note No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.
- Note Where both eyes are affected by the condition, a quantity of 2 units can be requested on the same authority prescription form.
- Note Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

**Authority required**
Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Initial treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**
- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing.

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 optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
SENSORY ORGANS

- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**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.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### aflibercept 4 mg/0.1 mL injection, 0.1 mL vial

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### aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe

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<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium</th>
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**AFLIBERCEPT**

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested on the same authority prescription form.

**Note** Pharmaceutical benefits that have the form aflibercept 0.09mL injection syringe and pharmaceutical benefits that have the form aflibercept 0.1mL injection vial are equivalent for the purposes of substitution.

**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**
- Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Applications for initial treatment of each eye must be made in writing.

A written application must include:
- a) a completed authority prescription form;
- b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**
Central retinal vein occlusion with macular oedema
Treatment Phase: Initial treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**
- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), AND
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, AND
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.
The first authority application for each eye must be made in writing.
A written application must include:
a) a completed authority prescription form;
b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
c) a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Central retinal vein occlusion with macular oedema
Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for the same eye, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### aflibercept 4 mg/0.1 mL injection, 0.1 mL vial

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### aflibercept 3.6 mg/0.09 mL injection, 0.09 mL syringe

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<th>MRVS$</th>
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**RANIBIZUMAB**

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.
**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.
**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested on the same authority prescription form.
**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority required**
Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Initial treatment

**Treatment criteria:**
Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:
- The condition must be due to age-related macular degeneration (AMD), AND
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.
The first authority application for each eye must be made in writing.
A written application must include:
- a completed authority prescription form;
- a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

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.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe
10138N

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ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial
1382R

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**RANIBIZUMAB**

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum number of repeats may be authorised.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

**Note** Where both eyes are affected by the condition, a quantity of 2 units can be requested on the same authority prescription form.

**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority required**
Diabetic macular oedema (DMO)
Treatment Phase: Initial treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:
- Patient must have visual impairment due to diabetic macular oedema, AND
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, AND
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, AND
• The treatment must be as monotherapy; OR
• The treatment must be in combination with laser photocoagulation, **AND**
• The treatment must be the sole PBS-subsidised therapy for this condition.

The first authority application for each eye must be made in writing.
A written application must include:

a) a completed authority prescription form;
b) a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
c) a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

**Diabetic macular oedema (DMO)**

**Treatment Phase:** Continuing treatment

**Treatment criteria:**

• Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

• Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
• The treatment must be as monotherapy; OR
• The treatment must be in combination with laser photocoagulation, **AND**
• The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

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**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

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**RANIBIZUMAB**

**Note** Special Pricing Arrangements apply.

**Note** No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.

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**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority required**

**Subfoveal choroidal neovascularisation (CNV)**

**Treatment Phase:** Initial treatment

**Treatment criteria:**

• Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**

• The condition must be due to pathologic myopia (PM), **AND**
• The condition must be diagnosed by optical coherence tomography; OR
• The condition must be diagnosed by fluorescein angiography, **AND**
• The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing.
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 optical coherence tomography or fluorescein angiogram report.
Note Any queries concerning the arrangements to prescribe may be directed to Services 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 and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

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Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Continuing treatment

Treatment criteria:
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:
- The condition must be due to pathologic myopia (PM), AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Initial treatment

Treatment criteria:
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:
- The condition must not be due to pathologic myopia,
- The condition must not be due to age-related macular degeneration,
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography,
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing.

A written application must include:
- a completed authority prescription form;
- b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Authority required

Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Continuing treatment

Treatment criteria:
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

Clinical criteria:
- The condition must not be due to pathologic myopia,
- The condition must not be due to age-related macular degeneration,
- The treatment must be the sole PBS-subsidised therapy for this condition,
- Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
RANIBIZUMAB

**Note** Special Pricing Arrangements apply.

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**Note** Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

### Authority required

Branch retinal vein occlusion with macular oedema

**Treatment Phase:** Initial treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**
- Patient must have visual impairment due to macular oedema secondary to branch retinal vein occlusion (BRVO), AND
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, AND
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority approval for initial treatment of each eye must be sought.

A written application must include:
- a) a completed authority prescription form;
- b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Reply Paid 9826
HOBART TAS 7001

### Authority required

Branch retinal vein occlusion with macular oedema

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for the same eye, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### Authority required

Central retinal vein occlusion with macular oedema

**Treatment Phase:** Initial treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**
- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), AND
• Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, AND
• The condition must be diagnosed by optical coherence tomography; OR
• The condition must be diagnosed by fluorescein angiography, AND
• The treatment must be the sole PBS-subsidised therapy for this condition. Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing.

A written application must include:
- a completed authority prescription form;
- a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

Note
Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**
Central retinal vein occlusion with macular oedema

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for the same eye, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Note
Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**ranibizumab 1.65 mg/0.165 mL injection, 0.165 mL syringe**

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<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
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**OTHER OPHTHALMOLOGICALS**

**Other ophthalmologicals**

**CARBOMER-974P**

**Authority required (STREAMLINED)**
6172

Severe dry eye syndrome

**Clinical criteria:**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**carbomer-974P 0.3% eye gel, 30 x 500 mg unit doses**

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**carbomer-974P 0.3% eye gel, 30 x 500 mg unit doses**

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**CARBOMER-980**

**Restricted benefit**

Severe dry eye syndrome, including Sjogren’s syndrome

**carbomer-980 0.2% eye gel, 10 g**

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†1
†2
CARBOMER-980

**Authority required (STREAMLINED)**

*6172*

Severe dry eye syndrome

**Clinical criteria:**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**CARBOMER-980**

- **Severe dry eye syndrome**
- **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.

**CARMELLOSE SODIUM**

- **Restricted benefit**
- Severe dry eye syndrome, including Sjogren's syndrome

**CARBOMER-980**

- **Severe dry eye syndrome**
- **Clinical criteria:**
  - Patient must be sensitive to preservatives in multi-dose eye drops.

**CARMELLOSE SODIUM**

- **Restricted benefit**
- Severe dry eye syndrome, including Sjogren's syndrome
### CARMELLOSE SODIUM

**Note** The in-use shelf life of Evolve carmellose 0.5% and Evolve hypromellose 0.3% is 3 months from the date of opening.

**Authority required (STREAMLINED)**

**6172**

Severe dry eye syndrome

**Clinical criteria:**
- Patient must be sensitive to preservatives in multi-dose eye drops.

### CARMELLOSE SODIUM + GLYCEROL

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**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.

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### General

carmellose sodium 1% eye drops, 30 x 0.4 mL unit doses

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carmellose sodium 1% eye drops, 30 x 0.4 mL unit doses

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carmellose sodium 0.5% eye drops, 30 x 0.4 mL unit doses

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carmellose sodium 0.5% eye drops, 30 x 0.4 mL unit doses

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### CARMELLOSE SODIUM

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**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.

### CARMELLOSE SODIUM + GLYCEROL

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

---

### CARMELLOSE SODIUM + GLYCEROL

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**
Severe dry eye syndrome, including Sjogren's syndrome

**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.

### Carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL

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#### 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>
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#### 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>
<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>15.56</td>
<td>16.85</td>
<td>a Tears Naturale [AQ]</td>
</tr>
</tbody>
</table>

#### DEXTRAN-70 + HYPROMELLOSE

**Authority required (STREAMLINED)**

**dextran-70 0.1% + hypromellose 0.3% eye drops, 28 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>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>..</td>
<td>36.93</td>
<td>38.22</td>
<td>Bion Tears [AQ]</td>
</tr>
</tbody>
</table>

#### DEXTRAN-70 + HYPROMELLOSE

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Severe dry eye syndrome, including Sjogren's syndrome

**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.

**dextran-70 0.1% + hypromellose 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>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡4.00</td>
<td>5</td>
<td>..</td>
<td>19.56</td>
<td>16.85</td>
<td>a Tears Naturale [AQ]</td>
</tr>
</tbody>
</table>

#### HYALURONATE SODIUM

**Note**

The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening.

**Authority required (STREAMLINED)**

**Hyaluronate sodium 0.1% 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>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>..</td>
<td>34.49</td>
<td>35.78</td>
<td>Hylo-Fresh [AE]</td>
</tr>
</tbody>
</table>
## SENSORY ORGANS

### Hyaluronate Sodium 0.1% 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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>34.49</td>
<td>35.78</td>
<td>Hylo-Fresh [AE]</td>
</tr>
</tbody>
</table>

### Hyaluronate Sodium 0.2% Eye Drops, 10 mL

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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>1</td>
<td>5</td>
<td>..</td>
<td>34.49</td>
<td>35.78</td>
<td>Hylo-Forte [AE]</td>
</tr>
</tbody>
</table>

### Hyaluronate Sodium 0.2% Eye Drops, 10 mL

<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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>34.49</td>
<td>35.78</td>
<td>Hylo-Forte [AE]</td>
</tr>
</tbody>
</table>

### HYPROMELLOSE

#### Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

### Hyaluronate Sodium 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>5</td>
<td>..</td>
<td>15.37</td>
<td>16.66</td>
<td>Methopt [AF]</td>
</tr>
</tbody>
</table>

### Hyaluronate Sodium 0.3% w/w 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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>14.26</td>
<td>15.55</td>
<td>In a Wink Moisturising [IQ]</td>
</tr>
</tbody>
</table>

### Hyaluronate Sodium 0.3% w/w 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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>14.26</td>
<td>15.55</td>
<td>Genteal [AQ]</td>
</tr>
</tbody>
</table>

### HYPROMELLOSE

#### Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

### Hyaluronate Sodium 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>
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<td>5</td>
<td>..</td>
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</tr>
</tbody>
</table>

### Hyaluronate Sodium 0.3% w/w Eye Drops, 10 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
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<th>MRVSN</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>14.26</td>
<td>15.55</td>
<td>In a Wink Moisturising [IQ]</td>
</tr>
</tbody>
</table>

### Hyaluronate Sodium 0.3% w/w 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>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>14.26</td>
<td>15.55</td>
<td>Genteal [AQ]</td>
</tr>
</tbody>
</table>

### HYPROMELLOSE

#### Note

The in-use shelf life of Evolve carmellose 0.5% and Evolve hypromellose 0.3% is 3 months from the date of opening.

#### Authority required (STREAMLINED)

6172
Severe dry eye syndrome

**Clinical criteria:**
- Patient must be sensitive to preservatives in multi-dose eye drops.

### Hyaluronate Sodium 0.3% w/w 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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>15.37</td>
<td>16.66</td>
<td>Methopt [AF]</td>
</tr>
</tbody>
</table>

### HYPROMELLOSE

#### Note

No increase in the maximum quantity or number of units may be authorised.

#### Note

No increase in the maximum number of repeats may be authorised.

#### Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

**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.

### Hyaluronate Sodium 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>5</td>
<td>..</td>
<td>15.37</td>
<td>16.66</td>
<td>Methopt [AF]</td>
</tr>
</tbody>
</table>
### Sensory Organs

#### General Pharmaceutical Benefits

<table>
<thead>
<tr>
<th>hypromellose 0.3% w/w eye drops, 10 mL</th>
<th>11643T</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>$1</td>
<td>11</td>
</tr>
<tr>
<td>$4,34</td>
<td>18.60</td>
</tr>
</tbody>
</table>

### HYPROMELLOSE + CARBOMER-980

**Restricted benefit**

Severe dry eye syndrome, including Sjogren’s syndrome

<table>
<thead>
<tr>
<th>hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g</th>
<th>5519L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>$1</td>
<td>5</td>
</tr>
<tr>
<td>$4,80</td>
<td>20.17</td>
</tr>
</tbody>
</table>

### HYPROMELLOSE + CARBOMER-980

**Restricted benefit**

Severe dry eye syndrome, including Sjogren’s syndrome

<table>
<thead>
<tr>
<th>hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g</th>
<th>8564R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>$1</td>
<td>5</td>
</tr>
<tr>
<td>$4,80</td>
<td>20.17</td>
</tr>
</tbody>
</table>

### HYPROMELLOSE + CARBOMER-980

**Restricted benefit**

Severe dry eye syndrome, including Sjogren’s syndrome

<table>
<thead>
<tr>
<th>hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g</th>
<th>9215B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>$1</td>
<td>11</td>
</tr>
<tr>
<td>$4,80</td>
<td>20.17</td>
</tr>
</tbody>
</table>

### OCRIPLASMIN

**Note** No increase in the maximum number of repeats may be authorised.

**Note** Special Pricing Arrangements apply.

**Authority required**

Vitreomacular traction syndrome

**Treatment criteria:**

- Must be treated by an ophthalmologist.
- Patient must have visual impairment due to vitreomacular traction (VMT) without a full thickness macular hole (FTMH); or
- Patient must have visual impairment due to vitreomacular traction (VMT) with a full thickness macular hole (FTMH) of a diameter of less than or equal to 400 micrometres, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 20/25 or worse in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography, **AND**
- The condition must have a vitreomacular adhesion diameter less than or equal to 1500 micrometres, **AND**
- Patient must not have an epiretinal membrane attached to the vitreomacular traction, **AND**
- The condition must be previously untreated in the eye proposed for treatment, **AND**
- Patient must not have received prior vitrectomy in the eye proposed for treatment, **AND**
- Patient must be symptomatic.

The prescriber must state which eye(s) is being treated at the time of application.

<table>
<thead>
<tr>
<th>ocriplasmin 500 microgram/0.2 mL injection, 0.2 mL vial</th>
<th>10947E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>1</td>
<td>...</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ocriplasmin 375 microgram/0.3 mL intraocular injection, 0.3 mL vial</th>
<th>11798Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>1</td>
<td>...</td>
</tr>
</tbody>
</table>
### Sensory Organs

#### Paraffin

<table>
<thead>
<tr>
<th>Paraffin 1 g/g eye ointment, 2 x 3.5 g</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>1750D</td>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>24.35</td>
<td>25.64</td>
<td>Poly Visc [IQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>* Refresh Night Time [AG]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Paraffin 1 g/g eye ointment, 2 x 3.5 g</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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</thead>
<tbody>
<tr>
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<td>‡1</td>
<td>5</td>
<td>..</td>
<td>24.35</td>
<td>25.64</td>
<td>Poly Visc [IQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>* Refresh Night Time [AG]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Paraffin 1 g/g eye ointment, 3.5 g</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>1754H</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>24.90</td>
<td>26.19</td>
<td>Poly Visc [IQ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Paraffin 1 g/g eye ointment, 3.5 g</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>5523Q</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>24.90</td>
<td>26.19</td>
<td>Poly Visc [IQ]</td>
</tr>
</tbody>
</table>

#### Paraffin

**Note** No increase in the maximum quantity or number of units may be authorised.
**Note** No increase in the maximum number of repeats may be authorised.

**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.

<table>
<thead>
<tr>
<th>Paraffin 1 g/g eye ointment, 2 x 3.5 g</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>9218E</td>
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<td>24.90</td>
<td>26.19</td>
<td>Poly Visc [IQ]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>* Refresh Night Time [AG]</td>
<td></td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Paraffin 1 g/g eye ointment, 3.5 g</th>
<th>Max Qty Packs</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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<tr>
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<td>..</td>
<td>24.90</td>
<td>26.19</td>
<td>Poly Visc [IQ]</td>
</tr>
</tbody>
</table>

#### Perfluorohexyloctane

**Note** The in-use shelf life of Novatears is 6 months from the date of opening.

**Authority required (STREAMLINED)**
6172
Severe dry eye syndrome

**Clinical criteria:**
- Patient must be sensitive to preservatives in multi-dose eye drops.

<table>
<thead>
<tr>
<th>Perfluorohexyloctane 100% eye drops, 3 mL</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>11439C</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>33.52</td>
<td>34.81</td>
<td>Novatears [AE]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Perfluorohexyloctane 100% eye drops, 3 mL</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>11446K</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>33.52</td>
<td>34.81</td>
<td>Novatears [AE]</td>
</tr>
</tbody>
</table>

#### Polyethylene Glycol-400 + Propylene Glycol

**Restricted benefit**
Severe dry eye syndrome, including Sjogren's syndrome

<table>
<thead>
<tr>
<th>Polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL</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>5524R</td>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>14.98</td>
<td>16.27</td>
<td>Systane [AQ]</td>
</tr>
</tbody>
</table>
### SENSORY ORGANS

**POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**

*Restricted benefit*

Severe dry eye syndrome, including Sjogren’s syndrome

<table>
<thead>
<tr>
<th>polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max.Qty Packs</strong></td>
</tr>
<tr>
<td>8676P</td>
</tr>
<tr>
<td>$1</td>
</tr>
</tbody>
</table>

**POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**

*Authority required (STREAMLINED)*

6172

Severe dry eye syndrome

Clinical criteria:

- Patient must be sensitive to preservatives in multi-dose eye drops.

<table>
<thead>
<tr>
<th>polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max.Qty Packs</strong></td>
</tr>
<tr>
<td>5532E</td>
</tr>
<tr>
<td>$2</td>
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</tbody>
</table>

**POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

<table>
<thead>
<tr>
<th>polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max.Qty Packs</strong></td>
</tr>
<tr>
<td>9219F</td>
</tr>
<tr>
<td>$†1</td>
</tr>
</tbody>
</table>

**POLYVINYL ALCOHOL**

*Restricted benefit*

Severe dry eye syndrome, including Sjogren’s syndrome

<table>
<thead>
<tr>
<th>polyvinyl alcohol 1.4% eye drops, 15 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max.Qty Packs</strong></td>
</tr>
<tr>
<td>2682E</td>
</tr>
</tbody>
</table>
| $†1 | 5 | .. | 15.37 | 16.66 | a PVA Tears [PE]
| | | | $†1.39 | 16.76 | 16.66 a Liquifilm Tears [AG]

**POLYVINYL ALCOHOL**

*Restricted benefit*

Severe dry eye syndrome, including Sjogren’s syndrome

<table>
<thead>
<tr>
<th>polyvinyl alcohol 1.4% eye drops, 15 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max.Qty Packs</strong></td>
</tr>
<tr>
<td>5526W</td>
</tr>
</tbody>
</table>
| $†1 | 5 | .. | 15.37 | 16.66 | a PVA Tears [PE]
| | | | $†1.39 | 16.76 | 16.66 a Liquifilm Tears [AG]

**POLYVINYL ALCOHOL**

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

<table>
<thead>
<tr>
<th>polyvinyl alcohol 1.4% eye drops, 15 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max.Qty Packs</strong></td>
</tr>
<tr>
<td>9220G</td>
</tr>
</tbody>
</table>
| $†1 | 11 | .. | 15.37 | 16.66 | a PVA Tears [PE]
| | | | $†1.39 | 16.76 | 16.66 a Liquifilm Tears [AG]

**RETINOL PALMITATE + PARAFFIN**

*Note* The in-use shelf life of VitA-POS is 6 months from the date of opening.
### Sensory Organs

#### Retinol Palmitate + Paraffin

<table>
<thead>
<tr>
<th>Schedule of Pharmaceutical Benefits – December 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Retinol Palmitate 0.0138% + Paraffin Eye Ointment, 5 g</strong></td>
</tr>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>2167C</td>
</tr>
</tbody>
</table>

#### Additional Notes:
- **Note**: The in-use shelf life of VitA-POS is 6 months from the date of opening.
- **Note**: No increase in the maximum quantity or number of units may be authorised.
- **Note**: No increase in the maximum number of repeats may be authorised.

#### Soy Lecithin + Tocopherol + Vitamin A

**Authority required (STREAMLINED)**

- **6172**: Severe dry eye syndrome

**Clinical criteria:**
- Patient must be sensitive to preservatives in multi-dose eye drops.

**Soy Lecithin 1% + Tocopherol 0.002% + Vitamin A Palmitate 0.025% Spray, 100 Actuations**

<table>
<thead>
<tr>
<th>Schedule of Pharmaceutical Benefits – December 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>5545W</td>
</tr>
</tbody>
</table>

**** 9448G | 2 | 5 | .. | 34.06 | 100% Tearsagain [RB] |

#### Otologicals

### Antiinfectives

#### Ciprofloxacin

**Authority required**

- Chronic suppurative otitis media

**Population criteria:**
- Patient must be an Aboriginal or a Torres Strait Islander person, **AND**
- Patient must be aged 1 month or older.

**Authority required**

- Chronic suppurative otitis media

**Population criteria:**
- Patient must be less than 18 years of age.

**Clinical criteria:**
- Patient must have perforation of the tympanic membrane.

**Authority required**

- Chronic suppurative otitis media

**Population criteria:**
- Patient must be less than 18 years of age.

**Clinical criteria:**
- Patient must have a grommet in situ.

**Ciprofloxacin 0.3% Ear Drops, 5 mL**

<table>
<thead>
<tr>
<th>Schedule of Pharmaceutical Benefits – December 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>2480M</td>
</tr>
</tbody>
</table>
FRAMYCETIN SULFATE + GRAMICIDIN + DEXAMETHASONE
framycetin sulfate 0.5% + gramicidin 0.005% + dexamethasone 0.05% ear drops, 8 mL

<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>2</td>
<td>..</td>
<td>15.08</td>
<td>16.37</td>
<td>* Otodex [AV]</td>
</tr>
</tbody>
</table>

TRIAMCINOLONE + NEOMYCIN + GRAMICIDIN + NYSTATIN
triamcinolone acetonide 0.09% + neomycin 0.225% + gramicidin 0.0225% + nystatin 90 000 units/mL ear drops, 7.5 mL

<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>2</td>
<td>..</td>
<td>16.08</td>
<td>17.37</td>
<td>* Otocomb Otic [LN]</td>
</tr>
</tbody>
</table>

triamcinolone acetonide 0.1% + neomycin 0.25% + gramicidin 0.025% + nystatin 100 000 units/g ointment, 5 g

<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>2</td>
<td>..</td>
<td>13.55</td>
<td>14.84</td>
<td>* Otocomb Otic [LN]</td>
</tr>
</tbody>
</table>

OPHTHALMOLOGICAL AND OTOTOLOGICAL PREPARATIONS

ANTIINFECTIVES

FRAMYCETIN SULFATE
framycetin sulfate 0.5% eye/ear drops, 8 mL

<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>2</td>
<td>..</td>
<td>15.08</td>
<td>16.37</td>
<td>Soframycin [SW]</td>
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</tbody>
</table>

framycetin sulfate 0.5% eye/ear drops, 8 mL

<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>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>2</td>
<td>..</td>
<td>15.08</td>
<td>16.37</td>
<td>Soframycin [SW]</td>
</tr>
</tbody>
</table>

VARIOUS

ALLERGENS

HONEY BEE VENOM
honey bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>296.46</td>
<td>41.00</td>
<td></td>
<td>Hymenoptera Honey Bee Venom [DE]</td>
</tr>
</tbody>
</table>

honey bee venom 550 microgram injection [1 vial] (&) inert substance diluent [3 x 1.8 mL vials], 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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>232.31</td>
<td>41.00</td>
<td></td>
<td>Albey Bee Venom [DE]</td>
</tr>
</tbody>
</table>

PAPER WASP VENOM

Note: Paper wasp venom is not European wasp venom

paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 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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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>232.31</td>
<td>41.00</td>
<td></td>
<td>Albey Paper Wasp Venom [DE]</td>
</tr>
</tbody>
</table>

paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 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>
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<tbody>
<tr>
<td>1</td>
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<td>346.72</td>
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<td>Hymenoptera Paper Wasp Venom [DE]</td>
</tr>
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</table>
### YELLOW JACKET VENOM

**yellow jacket venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 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>
</tr>
</thead>
<tbody>
<tr>
<td>2883R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Alphey Yellow Jacket Venom [DE]</td>
</tr>
</tbody>
</table>

**yellow jacket venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
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</tr>
</thead>
<tbody>
<tr>
<td>10622C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Hymenoptera Yellow Jacket Venom [DE]</td>
</tr>
</tbody>
</table>

### ALL OTHER THERAPEUTIC PRODUCTS

#### Antidotes

**naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules**

<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>10783M</td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>Junalox [JO]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>Naloxone Hydrochloride (DBL) [PF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>NALOXONE SXP [XC]</td>
</tr>
</tbody>
</table>

**naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules**

<table>
<thead>
<tr>
<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>
</tr>
</thead>
<tbody>
<tr>
<td>10787R</td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>Junalox [JO]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td>Naloxone Hydrochloride (DBL) [PF]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>NALOXONE SXP [XC]</td>
</tr>
</tbody>
</table>

**naloxone hydrochloride 1 mg/mL injection, 2 mL syringe**

<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>11077B</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Prenoxad [FF]</td>
</tr>
</tbody>
</table>

**naloxone hydrochloride 1 mg/mL injection, 2 mL syringe**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMO $</th>
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</tr>
</thead>
<tbody>
<tr>
<td>11078C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Prenoxad [FF]</td>
</tr>
</tbody>
</table>

**naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation**

<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>11816X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Nyxoid [MF]</td>
</tr>
</tbody>
</table>

**naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation**

<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>11817Y</td>
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<td></td>
<td>Nyxoid [MF]</td>
</tr>
</tbody>
</table>

### LANTHANUM

**Drugs for treatment of hyperkalemia and hyperphosphatemia**

**naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules**

<table>
<thead>
<tr>
<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>10783M</td>
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<td></td>
<td></td>
<td>*</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>Naloxone Hydrochloride (DBL) [PF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>NALOXONE SXP [XC]</td>
</tr>
</tbody>
</table>

**naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules**

<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>10787R</td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>Junalox [JO]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>Naloxone Hydrochloride (DBL) [PF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*</td>
<td>NALOXONE SXP [XC]</td>
</tr>
</tbody>
</table>

**naloxone hydrochloride 1 mg/mL injection, 2 mL syringe**

<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>11077B</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Prenoxad [FF]</td>
</tr>
</tbody>
</table>

**naloxone hydrochloride 1 mg/mL injection, 2 mL syringe**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<th>DPMO $</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11078C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Prenoxad [FF]</td>
</tr>
</tbody>
</table>

**naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation**

<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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</thead>
<tbody>
<tr>
<td>11816X</td>
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<td></td>
<td></td>
<td></td>
<td>Nyxoid [MF]</td>
</tr>
</tbody>
</table>

**naloxone 1.8 mg/actuation nasal spray, 2 x 1 actuation**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<tbody>
<tr>
<td>11817Y</td>
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<td></td>
<td></td>
<td></td>
<td>Nyxoid [MF]</td>
</tr>
</tbody>
</table>

### LANTHANUM

**LANTHANUM**

**Drugs for treatment of hyperkalemia and hyperphosphatemia**

**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.

**Authority required (STREAMLINED)**

**5491**

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 non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**Lanthanum 500 mg chewable tablet, 2 x 45**

<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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</thead>
<tbody>
<tr>
<td>9403X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fosrenol [TK]</td>
</tr>
</tbody>
</table>
### SEVELAMER

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note**
Pharmaceutical benefits that have the forms sevelamer hydrochloride 800 mg and sevelamer carbonate 800 mg tablet are equivalent for the purposes of substitution

**Authority required (STREAMLINED)**

#### 5491
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 non-calcium phosphate binding agents.

**Treatment criteria:**
- Patient must be undergoing dialysis for chronic kidney disease.

#### sevelamer hydrochloride 800 mg tablet, 180

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>231.45</td>
<td>41.00</td>
<td>* Renagel [GZ]</td>
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</table>

#### sevelamer carbonate 800 mg tablet, 180

<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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>231.45</td>
<td>41.00</td>
<td>* Sevelamer Apotex [TX]</td>
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</tbody>
</table>

#### SUCROFERRIC OXYHYDROXIDE

**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.

**Authority required (STREAMLINED)**

#### 5491
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 non-calcium phosphate binding agents.

**Treatment criteria:**
- Patient must be undergoing dialysis for chronic kidney disease.

#### sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90

<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>1</td>
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<td>411.06</td>
<td>41.00</td>
<td>Velphoro [VL]</td>
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**Detoxifying agents for antineoplastic treatment**

#### FOLINIC ACID

**folinic acid 100 mg/10 mL injection, 10 x 10 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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<td>59.11</td>
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</table>
VARIOUS

**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 300 mg/30 mL injection, 30 mL vial

<table>
<thead>
<tr>
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</table>

#### FOLINIC ACID

**Restricted benefit**

Megaloblastic anaemias

**Clinical criteria:**

- The condition must be a result of folic acid deficiency from the use of folic acid antagonists.

### folinic acid 50 mg/5 mL injection, 5 mL vial

<table>
<thead>
<tr>
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<tr>
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### folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules

<table>
<thead>
<tr>
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### MESNA

**Restricted benefit**

Urothelial toxicity

Treatment Phase: Prophylaxis or reduction of toxicity

**Clinical criteria:**

- The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide.

### mesna 1 g/10 mL injection, 15 x 10 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tr>
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### mesna 400 mg/4 mL injection, 15 x 4 mL ampoules

<table>
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<tr>
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<tr>
<td>8078E</td>
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<td>5</td>
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<td>83.54</td>
<td>Uromitexan [BX]</td>
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### PHOSPHORUS

**Authority required (STREAMLINED)**

- 5089 Hypophosphataemic rickets
- 5114 Vitamin D-resistant rickets
- 5095 Familial hypophosphataemia
- 5123 Hypercalcaemia

### phosphorus 500 mg effervescent tablet, 100

<table>
<thead>
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<tr>
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**Other therapeutic products**

---

### POLYLACTIC ACID

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

*Note* Authority applications 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).
VARIOUS

Authority required
Severe facial lipoatrophy
Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:
- The treatment must be for facial administration only, AND
- The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

c polylactic acid 150 mg injection, 1 vial

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
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<tr>
<td>2</td>
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<td>*385.92</td>
<td>41.00</td>
<td>Sculptra [GA]</td>
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</table>

POLYLACTIC ACID

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Maintenance treatment is limited to one re-treatment (maximum 2 vials) every 2 years.

Authority required
Severe facial lipoatrophy
Treatment Phase: Maintenance PBS-subsidised treatment

Clinical criteria:
- The treatment must be for facial administration only, AND
- The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

c polylactic acid 150 mg injection, 1 vial

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<th>DPMO $</th>
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<tr>
<td>2</td>
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<td>*385.92</td>
<td>41.00</td>
<td>Sculptra [GA]</td>
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DIAGNOSTIC AGENTS

URINE TESTS

GLUCOSE AND KETONE INDICATOR URINE

Restricted benefit
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

c glucose and ketone indicator urine diagnostic strip, 50

<table>
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<td>21.09</td>
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GLUCOSE INDICATOR URINE

Restricted benefit
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

c glucose indicator urine diagnostic strip, 50

<table>
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<td>*21.48</td>
<td>22.77</td>
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GENERAL NUTRIENTS

OTHER NUTRIENTS

MEDIUM CHAIN TRIGLYCERIDES

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)
6147
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 (STREAMLINED)
6191
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.

**Medium chain triglycerides oral liquid, 15 x 225 mL bottles**

<table>
<thead>
<tr>
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<td>*274.64</td>
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**MEDIUM CHAIN TRIGLYCERIDES**

*Note* No increase in the maximum quantity or number of units may be authorised.

*Note* No increase in the maximum number of repeats may be authorised.

**Clinical criteria:**
- Patient must have a condition due to liver disease; OR
- Patient must have a condition due to short gut syndrome; OR
- Patient must have a condition due to cystic fibrosis; OR
- Patient must have a condition due to gastrointestinal disorders.

**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.
• Patient must be aged from 1 to 10 years inclusive.

**protein formula with carbohydrate, fat, vitamins and minerals oral liquid, 12 x 500 mL bottles**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<tr>
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<td>..</td>
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<td>Nutrini Peptisorb Energy [NU]</td>
</tr>
</tbody>
</table>

- Fat/carbohydrates/proteins/minerals/vitamins, combinations

## AMINO ACID SYNTHETIC FORMULA

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

### Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**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 with oral steroids should not be commenced during the period of initial treatment.
- Eosinophilic oesophagitis is demonstrated by the following criteria:
  1. Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
  2. A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
  3. 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

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**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.
- 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.

### amino acid synthetic formula powder for oral liquid, 400 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>437.82</td>
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### amino acid synthetic formula powder for oral liquid, 400 g

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<td>437.82</td>
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## AMINO ACID SYNTHETIC FORMULA

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

### Authority required

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 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.

**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.
- 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

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.

Clinical criteria:
- The condition must not be isolated infant colic or reflux.

Population criteria:
- Patient must be up to the age of 24 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: Initial treatment for up to 6 months

Treatment criteria:
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:
- The condition must not be isolated infant colic or reflux.

Population criteria:
- Patient must be older than 24 months of age.
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

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.

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.
The name of the specialist and the date of birth of the patient must be included in the authority application.

<table>
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<tr>
<th>amino acid synthetic formula powder for oral liquid, 400 g</th>
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<tbody>
<tr>
<td><strong>1180D</strong> Max Qty Packs No. of Rpts Premium $ DPMO $ MRVSN $ Brand Name and Manufacturer</td>
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<td>8 5 .. *294.22 41.00 Neocate Junior Vanilla [SB]</td>
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<tr>
<td>8 5 .. *294.22 41.00 EleCare [AB]</td>
</tr>
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</table>

AMINO ACID SYNTHETIC FORMULA

Note
Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required
Cows’ milk anaphylaxis

Treatment criteria:
- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:
- Patient must be up to the age of 24 months.
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

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.

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.
The name of the specialist and the date of birth of the patient must be included in the authority application.
General Pharmaceutical Benefits

**Authority required**
Severe cows' milk protein enteropathy with failure to thrive
Treatment Phase: Continuing treatment

**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.

**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.
  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

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.

**Population criteria:**
- Patient must be older than 24 months of age.
  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

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**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.
  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.

**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS**

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

<table>
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<th>amino acid synthetic formula powder for oral liquid, 400 g</th>
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<td>8</td>
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**Authority required**
Cows' milk protein enteropathy
Treatment Phase: Initial treatment for up to 6 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.

**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.
  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

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.

Clinical criteria:
- The condition must not be isolated infant colic or reflux.

Population criteria:
- Patient must be up to the age of 24 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: Initial treatment for up to 6 months

Treatment criteria:
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:
- The condition must not be isolated infant colic or reflux.

Population criteria:
- Patient must be older than 24 months of age.

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

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.

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.

The name of the specialist and the date of birth of the patient must be included in the authority application.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g

<table>
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amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids powder for oral liquid, 400 g

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- AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

Note: Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required
Cows’ milk anaphylaxis

Treatment criteria:
- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:
- Patient must be up to the age of 24 months.
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

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.

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. 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

**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.

**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. The name of the specialist and the date of birth of the patient must be included in the authority application.

**Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein**
Treatment Phase: Continuing treatment

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.
- 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. The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Eosinophilic oesophagitis
Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**
- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**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 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

Treatment criteria:
• Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

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.

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.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides powder for oral liquid, 400 g

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• AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required
Cows’ milk protein enteropathy
Treatment Phase: Initial treatment for up to 6 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.

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.
  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

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.

Clinical criteria:
• The condition must not be isolated infant colic or reflux.

Population criteria:
• Patient must be up to the age of 24 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: Initial treatment for up to 6 months

Treatment criteria:
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Clinical criteria:
• The condition must not be isolated infant colic or reflux.

Population criteria:
• Patient must be older than 24 months of age.
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

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.

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.
The name of the specialist and the date of birth of the patient must be included in the authority application.

AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Note: Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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Cows’ milk anaphylaxis
Treatment criteria:
• Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Population criteria:
• Patient must be up to the age of 24 months.

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

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.

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 an 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.
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

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.

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.
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

Treatment criteria:
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

Clinical criteria:
• The condition must not be isolated infant colic or reflux.

Population criteria:
• Patient must be older than 24 months of age.
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

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**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.
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.

*AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES*

**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**

**Notes:**
- Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.
• Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**
• Patient must be up to the age of 24 months.

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

**Treatment criteria:**
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**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.

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.

**Authority required**
Eosinophilic oesophagitis

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
• Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**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.

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.

### AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Treatment Phase:** Initial treatment for up to 6 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.

**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.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Cows’ milk protein enteropathy

**Treatment Phase:** Initial treatment for up to 6 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.

**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.

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

**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.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.

**Population criteria:**
- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

**Treatment Phase:** Initial treatment for up to 6 months

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.

**Population criteria:**
- Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

**Treatment Phase:** Initial treatment for up to 6 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.

**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.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Eosinophilic oesophagitis

**Treatment Phase:** Initial treatment for up to 3 months

**Treatment criteria:**
- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**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 with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:
- Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
- 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.

**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**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**
Cows' milk protein enteropathy and intolerance to soy protein

**Treatment Phase:** Initial treatment

**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.

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.

Authority required (STREAMLINED)

6193
Cows' milk protein enteropathy and intolerance to soy protein
Treatment Phase: Continuing treatment

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.

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.

Authority required (STREAMLINED)

6204
Cows' milk protein enteropathy and intolerance to soy protein
Treatment Phase: Continuing treatment

Treatment criteria:
• Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

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.
The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)

6137
Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment Phase: Initial treatment for up to 6 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.

Population criteria:
• Patient must be up to the age of 24 months.
The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)

6182
Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment Phase: Continuing treatment

Treatment criteria:
• Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

Population criteria:
• Patient must be up to the age of 24 months.
The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)

6194
Biliary atresia

Authority required (STREAMLINED)

6157
Chronic liver failure with fat malabsorption

Authority required (STREAMLINED)

6205
Chylous ascites

Authority required (STREAMLINED)

6195
Cystic fibrosis

Authority required (STREAMLINED)
6158
Enterokinase deficiency

Authority required (STREAMLINED)

6166
Proven fat malabsorption

Authority required (STREAMLINED)

6148
Severe diarrhoea of greater than 2 weeks duration

Population criteria:
- Patient must be aged less than 4 months.

Authority required (STREAMLINED)

6138
Severe intestinal malabsorption including short bowel syndrome

PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES powder for oral liquid, 450 g

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Note: No increase in the maximum quantity or number of units may be authorised.

Authority required (STREAMLINED)

6174
Cows’ milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

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.

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.

Authority required (STREAMLINED)

6193
Cows’ milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

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.

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 older than 24 months.

The name of the specialist must be documented in the patient’s medical records

Authority required (STREAMLINED)

6204
Cows’ milk protein enteropathy and intolerance to soy protein

Treatment criteria:
- Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

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.

Authority required (STREAMLINED)

6137
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 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.

**Population criteria:**
- Patient must be up to the age of 24 months.
The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

6182
Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Population criteria:**
- Patient must be up to the age of 24 months.
The name of the specialist must be documented in the patient's medical records

**Authority required (STREAMLINED)**

6194
Biliary atresia

**Authority required (STREAMLINED)**

6157
Chronic liver failure with fat malabsorption

**Authority required (STREAMLINED)**

6205
Chylous ascites

**Authority required (STREAMLINED)**

6195
Cystic fibrosis

**Authority required (STREAMLINED)**

6158
Enterokinase deficiency

**Authority required (STREAMLINED)**

6166
Proven fat malabsorption

**Authority required (STREAMLINED)**

6148
Severe diarrhoea of greater than 2 weeks duration

**Population criteria:**
- Patient must be aged less than 4 months.

**Authority required (STREAMLINED)**

6138
Severe intestinal malabsorption including short bowel syndrome

**Authority required (STREAMLINED)**

6206
Chylothorax

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**TRIGLYCERIDES MEDIUM CHAIN FORMULA**

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised.

Note Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**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.

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**protein hydrolysate formula with medium chain triglycerides powder for oral liquid, 400 g**

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**triglycerides medium chain formula powder for oral liquid, 400 g**

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triglycerides medium chain formula powder for oral liquid, 400 g

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triglycerides medium chain formula oral liquid, 8 x 500 mL pouches

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</table>

**TRIGLYCERIDES MEDIUM CHAIN FORMULA**

*Note* No increase in the maximum number of repeats may be authorised.

*Note* Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

*Note* Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**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.

**Carbohydrates**

- **MODIFIED LONG CHAIN AMYLOPECTIN**
  - **Restricted benefit**
    - Hyperlipoproteinaemia type 1
  - **Restricted benefit**
    - Long chain fatty acid oxidation disorders
  - **Restricted benefit**
    - Chylous ascites
  - **Restricted benefit**
    - Chylothorax

**Amino acids/carbohydrates/minerals/vitamins, combinations**

**AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES**

*Authority required*

Cows’ milk protein enteropathy

*Treatment Phase: Initial treatment for up to 6 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.

**Clinical criteria:**
VARIOUS

- 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.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Severe cows’ milk protein enteropathy with failure to thrive

**Treatment Phase:** Initial treatment for up to 6 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.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.

**Population criteria:**
- Patient must be up to the age of 24 months.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae

**Treatment Phase:** Initial treatment for up to 6 months

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.

**Population criteria:**
- Patient must be older than 24 months of age.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein

**Treatment Phase:** Initial treatment for up to 6 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.

**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.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Eosinophilic oesophagitis

**Treatment Phase:** Initial treatment for up to 3 months

**Treatment criteria:**
- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**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 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.

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

### Amino Acid Formula with Fat, Carbohydrate, Vitamins, Minerals, Trace Elements and Medium Chain Triglycerides Powder for Oral Liquid, 400 g

<table>
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<th>Authority</th>
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**AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES**

**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**

**Cows’ milk protein enteropathy**

Treatment Phase: Continuing treatment

**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.

**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.
- 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

**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.

**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.
- 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

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.

**Population criteria:**
- Patient must be older than 24 months of age.
- 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

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**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.
- 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**

Treatment criteria:
• Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**
• Patient must be up to the age of 24 months.

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**
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.

**Authority required**
Eosinophilic oesophagitis
Treatment Phase: Continuing treatment

**Treatment criteria:**
• Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**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.

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.

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**amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides powder for oral liquid, 400 g**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>Alfamino Junior [NT]</td>
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<table>
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<th>Brand Name and Manufacturer</th>
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</thead>
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<tr>
<td>Neocate Junior [SB]</td>
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</table>

**Milk substitutes**

### MILK POWDER SYNTHETIC LOW CALCIUM

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

**Restricted benefit**

Hypercalcaemia

**Population criteria:**
• Patient must be under the age of 4 years.

**milk powder synthetic low calcium powder for oral liquid, 400 g**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>Locasol [SB]</td>
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**Other combinations of nutrients**

### AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS

**Note** Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

**Authority required**

Eosinophilic oesophagitis
Treatment Phase: Initial treatment for up to 3 months

**Treatment criteria:**
• Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**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 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

**Treatment criteria:**

- Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

**Clinical criteria:**

- Patient must have responded to an initial course of PBS-subsidised treatment.

**Population 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.

---

**AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS**

**Note** No increase in the maximum quantity or number of units may be authorised.

**Note** No increase in the maximum number of repeats may be authorised.

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- **Neocate Syneo [SB]**
  - **AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS**
  - **Note** No increase in the maximum quantity or number of units may be authorised.
  - **Note** No increase in the maximum number of repeats may be authorised.

**Authority required**

**Cows' milk protein enteropathy**

**Treatment Phase:** Initial treatment for up to 6 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.

**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.

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

**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.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be up to the age of 24 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:** Initial treatment for up to 6 months

**Treatment criteria:**

- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

**Clinical criteria:**

- The condition must not be isolated infant colic or reflux.

**Population criteria:**

- Patient must be older than 24 months of age.

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
**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.

**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.
- The name of the specialist and the date of birth of the patient must be included in the authority application.

### amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g

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<th>Max Qty Packs</th>
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<td>336.22</td>
<td>41.00</td>
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**Note** Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

**Authority required**
- Cows’ milk anaphylaxis

**Treatment criteria:**
- Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

**Population criteria:**
- Patient must be up to the age of 24 months.
- 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

**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.

**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.
- 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

**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.

**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.
- 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

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.

**Population criteria:**
- Patient must be older than 24 months of age.
- 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
Treatment criteria:
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

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.
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 A risk/benefit analysis prior to treatment, and continuous patient monitoring from a health care professional is required for the use of this product, for this indication.

| Amino acid formula supplemented with prebiotics, probiotics and long chain polyunsaturated fatty acids powder for oral liquid, 400 g |
|---|---|---|---|---|---|
| 11340W | Max Qty Packs | No of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 8 | 5 | .. | *336.22 | 41.00 | | Neocate Syneo [SB] |

### AMINO ACID FORMULA WITH CARBOHYDRATE WITHOUT PHENYLALANINE

**Note** This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition.

| Amino acid formula with carbohydrate without phenylalanine modified release tablet, 6 x 77 |
|---|---|---|---|---|---|
| 12072J | Max Qty Packs | No of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 4 | 5 | .. | *1338.26 | 41.00 | | PKU Easy Tablet [OH] |

### AMINO ACID FORMULA WITH CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE

| Amino acid formula with carbohydrate, vitamins, minerals and trace elements without phenylalanine powder for oral liquid, 30 x 20 g sachets |
|---|---|---|---|---|---|
| 10806R | Max Qty Packs | No of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 4 | 5 | .. | *1017.06 | 41.00 | | PKU Go [OH] |

### AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT METHIONINE

**Note** This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition.

| Amino acid formula with fat, carbohydrate without methionine modified release tablet, 6 x 77 |
|---|---|---|---|---|---|
| 12006X | Max Qty Packs | No of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 5 | 5 | .. | *2977.14 | 41.00 | | HCU Easy Tablet [OH] |

### AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE

**Note** This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition.

| Amino acid formula with fat, carbohydrate without phenylalanine tablet: modified release, 4 x 110 g |
|---|---|---|---|---|---|
| 10683G | Max Qty Packs | No of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 7 | 5 | .. | *1959.76 | 41.00 | | PKU Easy Microtabs [OH] |

### AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE AND TYROSINE

**Note** This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition.

| Amino acid formula with fat, carbohydrate without phenylalanine and tyrosine modified release tablet, 6 x 77 |
|---|---|---|---|---|---|
| 12015J | Max Qty Packs | No of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 4 | 5 | .. | *2417.10 | 41.00 | | TYR Easy Tablet [OH] |
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT VALINE, LEUCINE AND ISOLEUCINE

Note: This product does not contain any vitamins, minerals or trace elements and is not intended as a sole source of nutrition.

Restricted benefit
Maple syrup urine disease

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<th>No. of Rpts</th>
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<td>6</td>
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<td>..</td>
<td>*2977.14</td>
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AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

Note: The level of iron in this product is below the recommended daily intake (RDI) for infants and should be supplemented by other sources where appropriate.

Restricted benefit
Phenylketonuria

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Maximum Quantity</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>
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<td>10822N</td>
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<td>500 mL bottles</td>
<td>..</td>
<td>*645.10</td>
<td>41.00</td>
<td>PKU Baby [OH]</td>
</tr>
</tbody>
</table>

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>Product Description</th>
<th>Maximum Quantity</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>Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without methionine and supplemented with docosahexaenoic acid oral liquid</td>
<td>3417W</td>
<td>36</td>
<td>125 mL bottles</td>
<td>..</td>
<td>*2420.50</td>
<td>41.00</td>
<td>HCU Anamix junior LQ [SB]</td>
</tr>
</tbody>
</table>

AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE

Restricted benefit
Phenylketonuria

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Maximum Quantity</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>Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine oral liquid: powder for</td>
<td>10632N</td>
<td>30</td>
<td>34 g bottles</td>
<td>..</td>
<td>*1935.59</td>
<td>41.00</td>
<td>PKU Easy Shake &amp; Go [OH]</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>Product Description</th>
<th>Maximum Quantity</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>Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid oral liquid</td>
<td>9330C</td>
<td>36</td>
<td>125 mL bottles</td>
<td>..</td>
<td>*2196.14</td>
<td>41.00</td>
<td>TYR Anamix junior LQ [SB]</td>
</tr>
</tbody>
</table>

AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS, WITHOUT PHENYLALANINE AND TYROSINE

Restricted benefit
Tyrosinaemia

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Maximum Quantity</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>Amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements, without phenylalanine and tyrosine powder for oral liquid</td>
<td>10934L</td>
<td>30</td>
<td>34 g bottles</td>
<td>..</td>
<td>*2981.38</td>
<td>41.00</td>
<td>TYR Easy Shake &amp; Go [OH]</td>
</tr>
</tbody>
</table>

AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

Restricted benefit
### AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

Proven glutaric aciduria type 1

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Premium</th>
</tr>
</thead>
<tbody>
<tr>
<td>GA1 Anamix Junior [NU]</td>
<td></td>
<td></td>
<td>*1847.18</td>
</tr>
</tbody>
</table>

#### Alternate Formulations

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**

**Restricted benefit**

Proven glutaric aciduria type 1

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Premium</th>
</tr>
</thead>
<tbody>
<tr>
<td>GA1 Anamix infant [SB]</td>
<td></td>
<td></td>
<td>*665.58</td>
</tr>
</tbody>
</table>

#### Alternate Formulations

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**

**Restricted benefit**

Proven glutaric aciduria type 1

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<th>Brand Name and Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Premium</th>
</tr>
</thead>
<tbody>
<tr>
<td>GA1 Anamix [SB]</td>
<td></td>
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<td>*2684.52</td>
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</tbody>
</table>

### AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

Pyridoxine non-responsive homocystinuria

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Premium</th>
</tr>
</thead>
<tbody>
<tr>
<td>GA1 Anamix [VF]</td>
<td></td>
<td></td>
<td>*1847.26</td>
</tr>
</tbody>
</table>

#### Alternate Formulations

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE**

**Restricted benefit**

Pyridoxine non-responsive homocystinuria

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Premium</th>
</tr>
</thead>
<tbody>
<tr>
<td>GA gel [VF]</td>
<td></td>
<td></td>
<td>*2748.86</td>
</tr>
</tbody>
</table>

#### Alternate Formulations
### Amino Acid Formula with Vitamins and Minerals Without Methionine

**Amino Acid Formula with Vitamins and Minerals Without Methionine 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>HCU Anamix Junior [NU]</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>1758.94</td>
<td>41.00</td>
</tr>
</tbody>
</table>

**Restricted benefit**
- Pyridoxine non-responsive homocystinuria

**Population criteria:**
- Patient must be an infant or a very young child.

### Amino Acid Formula with Vitamins and Minerals Without Methionine Powder for Oral Liquid, 400 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>
</tr>
</thead>
<tbody>
<tr>
<td>HCU Anamix infant [SB]</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>632.62</td>
<td>41.00</td>
</tr>
</tbody>
</table>

**Restricted benefit**
- Methylmalonic acidemia
- Propionic acidemia

### Amino Acid Formula with Vitamins and Minerals Without Methionine, Threonine and Valine and Low in Isoleucine

<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>MMA/PA Anamix infant [SB]</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>2255.02</td>
<td>41.00</td>
</tr>
<tr>
<td>MMA/PA gel [VF]</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>1758.94</td>
<td>41.00</td>
</tr>
<tr>
<td>MMA/PA express 15 [VF]</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>2574.74</td>
<td>41.00</td>
</tr>
</tbody>
</table>

**Restricted benefit**
- Methylmalonic acidemia
- Propionic acidemia

### Amino Acid Formula with Vitamins and Minerals Without Methionine, Threonine and Valine and Low in Isoleucine Powder for Oral Liquid, 30 x 24 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>MMA/PA Anamix Junior [NU]</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>1758.86</td>
<td>41.00</td>
</tr>
</tbody>
</table>

**Restricted benefit**
- Methylmalonic acidemia
- Propionic acidemia

### Amino Acid Formula with Vitamins and Minerals Without Methionine, Threonine and Valine and Low in Isoleucine Powder for Oral Liquid, 30 x 24 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>PKU Anamix Junior LQ [SB]</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>1056.86</td>
<td>41.00</td>
</tr>
</tbody>
</table>

**Restricted benefit**
- Phenylketonuria

### Amino Acid Formula with Vitamins and Minerals Without Phenylalanine

<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 Junior LQ [SB]</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>1285.26</td>
<td>41.00</td>
</tr>
</tbody>
</table>

**Restricted benefit**
- Phenylketonuria

### Amino Acid Formula with Vitamins and Minerals Without Phenylalanine oral liquid, 36 x 125 mL bottles

<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 Junior LQ [SB]</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>1056.86</td>
<td>41.00</td>
</tr>
</tbody>
</table>

### Amino Acid Formula with Vitamins and Minerals Without Phenylalanine oral liquid, 30 x 130 mL 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>
</tr>
</thead>
<tbody>
<tr>
<td>PKU Cooler 15 [VF]</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>1285.26</td>
<td>41.00</td>
</tr>
</tbody>
</table>
**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE**

**Note** Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

### 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>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PKU Lophlex LQ 10 [SB]</td>
<td>2</td>
<td>5</td>
<td>*871.28</td>
<td>41.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PKU Lophlex LQ 20 [SB]</td>
<td>1</td>
<td>5</td>
<td>1124.62</td>
<td>41.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PKU Lophlex LQ 10 [SB]</td>
<td>1</td>
<td>5</td>
<td>1124.62</td>
<td>41.00</td>
<td></td>
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<td>1</td>
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<td></td>
</tr>
</tbody>
</table>

- **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE**
  - **Note** Pharmaceutical benefits that have the brand and form PKU Lophlex 27.8 g, 30 sachets and pharmaceutical benefits that have the brand and form PKU Lophlex 28 g, 30 g sachets are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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</tr>
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<tbody>
<tr>
<td>PKU Anamix Junior [SB]</td>
<td>1</td>
<td>5</td>
<td>1124.62</td>
<td>41.00</td>
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<td></td>
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</tbody>
</table>

### Restricted benefit
Phenylketonuria

<table>
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</tr>
</tbody>
</table>

- **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE**
  - **Note** Pharmaceutical benefits that have the brand and form PKU Lophlex 27.8 g, 30 sachets and pharmaceutical benefits that have the brand and form PKU Lophlex 28 g, 30 g sachets are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<td>5</td>
<td>1124.62</td>
<td>41.00</td>
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</tr>
<tr>
<td>PKU Anamix Junior [SB]</td>
<td>1</td>
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<td>1124.62</td>
<td>41.00</td>
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<td>PKU Anamix Junior [SB]</td>
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<td>5</td>
<td>1124.62</td>
<td>41.00</td>
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<tr>
<td>PKU Anamix Junior [SB]</td>
<td>1</td>
<td>5</td>
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<td>PKU Anamix Junior [SB]</td>
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<tr>
<td>PKU Anamix Junior [SB]</td>
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<td>41.00</td>
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</tr>
<tr>
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<td>1124.62</td>
<td>41.00</td>
<td></td>
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</tr>
<tr>
<td>PKU Anamix Junior [SB]</td>
<td>1</td>
<td>5</td>
<td>1124.62</td>
<td>41.00</td>
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</tr>
</tbody>
</table>

### Restricted benefit
Phenylketonuria
### AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

#### Restricted benefit

Tyrosinaemia

<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>
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<td>41.00</td>
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<tr>
<td>PKU Lophlex [SB]</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>1688.10</td>
<td>41.00</td>
</tr>
</tbody>
</table>

#### AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

#### Restricted benefit

Tyrosinaemia

### 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

**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 cooler 10 [VF]</td>
<td>2651M</td>
<td>4</td>
<td>5</td>
<td>*1758.94</td>
<td>41.00</td>
</tr>
<tr>
<td>MSUD cooler 20 [VF]</td>
<td>2654Q</td>
<td>4</td>
<td>5</td>
<td>*3373.98</td>
<td>41.00</td>
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<tr>
<td>MSUD Anamix infant [SB]</td>
<td>2380G</td>
<td>8</td>
<td>5</td>
<td>*632.62</td>
<td>41.00</td>
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<tr>
<td>MSUD Lophlex LQ 20 [SB]</td>
<td>1546J</td>
<td>3</td>
<td>5</td>
<td>*2574.69</td>
<td>41.00</td>
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<tr>
<td>MSUD Anamix Junior [SB]</td>
<td>2375B</td>
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<td>5</td>
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<td>41.00</td>
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<tr>
<td>MSUD Maxamum [SB]</td>
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<td>5</td>
<td>*2255.02</td>
<td>41.00</td>
</tr>
<tr>
<td>MSUD AID III [SB]</td>
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<td>4</td>
<td>5</td>
<td>*2228.38</td>
<td>41.00</td>
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<tr>
<td>MSUD gel [VF]</td>
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<td>5</td>
<td>*1758.94</td>
<td>41.00</td>
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<tr>
<td>MSUD express 15 [VF]</td>
<td>8632H</td>
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<td>5</td>
<td>*2574.74</td>
<td>41.00</td>
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<tr>
<td>MSUD express 20 [VF]</td>
<td>1914R</td>
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<td>5</td>
<td>*3383.54</td>
<td>41.00</td>
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</tbody>
</table>

**Note**
Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

<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>10259Y</td>
<td>4</td>
<td>5</td>
<td>*1758.94</td>
<td>41.00</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><em>MSUD Anamix Junior LQ [SB]</em></td>
<td>4</td>
<td>5</td>
<td>..</td>
<td><em>2196.14</em></td>
<td>41.00</td>
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</table>

### AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID

**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><em>PKU Explore 10 [VF]</em></td>
<td>4</td>
<td>5</td>
<td>..</td>
<td><em>1017.02</em></td>
<td>41.00</td>
</tr>
<tr>
<td><em>PKU Anamix First Spoon [SB]</em></td>
<td>8</td>
<td>5</td>
<td>..</td>
<td><em>1017.02</em></td>
<td>41.00</td>
</tr>
<tr>
<td><em>PKU Explore 5 [VF]</em></td>
<td>8</td>
<td>5</td>
<td>..</td>
<td><em>1017.02</em></td>
<td>41.00</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><em>PKU Anamix infant [SB]</em></td>
<td>8</td>
<td>5</td>
<td>..</td>
<td><em>578.70</em></td>
<td>41.00</td>
</tr>
</tbody>
</table>

### AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE

**Note** The level of iron in this product is below the recommended daily intake (RDI) for infants and should be supplemented by other sources where appropriate.

<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><em>PKU Start [VF]</em></td>
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<td>5</td>
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<td><em>615.18</em></td>
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### 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>
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<tbody>
<tr>
<td><em>Phlexy-10 [SB]</em></td>
<td>24</td>
<td>5</td>
<td>..</td>
<td><em>1185.66</em></td>
<td>41.00</td>
</tr>
</tbody>
</table>

### AMINO ACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE

**Restricted benefit**
Maple syrup urine disease
**Amino Acid Formula Without Valine, Leucine and Isoleucine Containing 5 g of Protein Equivalent Powder for Oral Liquid, 30 x 6 g Sachets**

<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>10161T</td>
<td>12</td>
<td>5</td>
<td>..</td>
<td>2981.34</td>
<td>41.00</td>
<td>MSUD amino5 [VF]</td>
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</tbody>
</table>

**ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE**

**Restricted Benefit**

Peroxisomal biogenesis disorders

**Arachidonic Acid and Docosahexaenoic Acid with Carbohydrate Containing 200 mg Arachidonic Acid and 100 mg Docosahexaenoic Acid Oral Liquid: Powder for, 30 x 4 g Sachets**

<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>10036F</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>352.50</td>
<td>41.00</td>
<td>Keyomega [VF]</td>
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</tbody>
</table>

**ARGININE WITH CARBOHYDRATE**

**Note** Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

**Restricted Benefit**

Urea cycle disorders

**Arginine with Carbohydrate Containing 2 g Arginine Oral Liquid: Powder for, 30 x 4 g Sachets**

<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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<tr>
<td>5482M</td>
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<td>..</td>
<td>666.90</td>
<td>41.00</td>
<td>Arginine 2000 [VF]</td>
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</table>

**Arginine with Carbohydrate Containing 500 mg Arginine Oral Liquid: Powder for, 30 x 4 g Sachets**

<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>9437Q</td>
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<td>5</td>
<td>..</td>
<td>446.94</td>
<td>41.00</td>
<td>Arginine 500 [VF]</td>
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**Arginine with Carbohydrate Containing 5 g Arginine Oral Liquid: Powder for, 30 x 7.6 g Sachets**

<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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<tr>
<td>10093F</td>
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<td>5</td>
<td>..</td>
<td>884.70</td>
<td>41.00</td>
<td>Arginine 5000 [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 Powder for Oral Liquid, 400 g**

<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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<tr>
<td>8369L</td>
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<td>257.58</td>
<td>41.00</td>
<td>Energivit [SB]</td>
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</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 200 Kilocalories Powder for Oral Liquid, 30 x 43 g Sachets**

<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>10039J</td>
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<td>5</td>
<td>..</td>
<td>453.66</td>
<td>41.00</td>
<td>Basecal 200 [VF]</td>
</tr>
</tbody>
</table>

**CITRULLINE**

**Note** Citrulline is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism

**Restricted Benefit**

Urea cycle disorders

**Clinical criteria:**

- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

**Citrulline 1 g Tablet, 300**

<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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<tr>
<td>10736C</td>
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<td>5</td>
<td>..</td>
<td>1216.91</td>
<td>41.00</td>
<td>Citrulline Easy [OH]</td>
</tr>
</tbody>
</table>
## CITRULLINE WITH CARBOHYDRATE

**Note** Citrulline with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

<table>
<thead>
<tr>
<th>Restricted benefit</th>
<th>Urea cycle disorders</th>
</tr>
</thead>
</table>

**Clinical criteria:**
- The treatment must be for preventing low plasma arginine levels; OR
- The treatment must be for preventing low citrulline levels.

<p>| Citrulline with carbohydrate containing 1 g citrulline powder for oral liquid, 30 x 4 g sachets |</p>
<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>5481L</td>
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<td>5</td>
<td>..</td>
<td>*495.78</td>
<td>Citrulline 1000 [VF]</td>
</tr>
</tbody>
</table>

## DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE

**Restricted benefit**
- Peroxisomal biogenesis disorders

<p>| Docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4g sachets |</p>
<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>10040K</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*352.50</td>
<td>Docomega [VF]</td>
</tr>
</tbody>
</table>

## ESSENTIAL AMINO ACIDS FORMULA

**Restricted benefit**
- Gyrate atrophy of the choroid and retina

<p>| Essential amino acids formula powder for oral liquid, 2 x 200 g |</p>
<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>9329B</td>
<td>6</td>
<td>5</td>
<td>..</td>
<td>*1047.78</td>
<td>Essential Amino Acid Mix [SB]</td>
</tr>
</tbody>
</table>

## ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS AND VITAMIN C

**Restricted benefit**
- Gyrate atrophy of the choroid and retina

<p>| Essential amino acids formula with minerals and vitamin C powder for oral liquid, 400 g |</p>
<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>2027Q</td>
<td>5</td>
<td>5</td>
<td>..</td>
<td>*521.84</td>
<td>Dialamine [SB]</td>
</tr>
</tbody>
</table>

## ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS

**Restricted benefit**
- Gyrate atrophy of the choroid and retina

<p>| Essential amino acids formula with vitamins and minerals powder for oral liquid, 50 x 12.5 g sachets |</p>
<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>9385Y</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*1321.22</td>
<td>EAA Supplement [VF]</td>
</tr>
</tbody>
</table>

## GLYCINE WITH CARBOHYDRATE

**Restricted benefit**
- Isovaleric acidemia

<p>| Glycine with carbohydrate containing 500 mg glycine powder for oral liquid, 30 x 4 g sachets |</p>
<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>10195N</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*495.78</td>
<td>Glycine500 [VF]</td>
</tr>
</tbody>
</table>

## GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACID FORMULA WITH VITAMINS, MINERALS, AND LOW IN TYROSINE AND PHENYLALANINE

**Restricted benefit**
- Tyrosinaemia
### GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

#### Restricted benefit

**Tyrosinaemia**
glycomacropeptide and essential amino acids formula with vitamins, minerals, and low in tyrosine and phenylalanine powder for oral liquid, 30 x 31 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>12175</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>3373.98</td>
<td>Tylactin Build 20 [QH]</td>
</tr>
</tbody>
</table>

glycomacropeptide and essential amino acid formula with vitamins, minerals, and low in tyrosine and phenylalanine powder for oral liquid, 30 x 35 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>11832R</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>4112.98</td>
<td>TYR Sphere20 [VF]</td>
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</tbody>
</table>

#### Restricted benefit

**Phenylketonuria**
glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 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>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1052BD</td>
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<td>..</td>
<td>3128.98</td>
<td>Tylactin RTD [QH]</td>
</tr>
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</table>

glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent bar, 14 x 81 g

<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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<tbody>
<tr>
<td>11290F</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>2932.14</td>
<td>Tylactin Complete [QH]</td>
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</table>

#### Restricted benefit

**Phenylketonuria**
glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g protein oral liquid, 30 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>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>10332T</td>
<td>4</td>
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<td>1595.50</td>
<td>PKU Glytactin RTD 15 [QH]</td>
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</table>

glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent oral liquid, 30 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>
<th>Brand Name and Manufacturer</th>
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</thead>
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<tr>
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<td>5</td>
<td>..</td>
<td>2100.54</td>
<td>PKU Bettermilk Lite [QH]</td>
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</tbody>
</table>

glycomacropeptide and essential amino acids with vitamins and minerals powder for oral liquid, 60 x 20 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>11084J</td>
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<td>5</td>
<td>..</td>
<td>1332.99</td>
<td>PKU Restore [QH]</td>
</tr>
</tbody>
</table>

**Note** This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.

**Note** This product is low in folic acid, choline and methionine and is not intended as a sole source of nutrition.
glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g of protein equivalent powder for oral liquid, 60 x 16 g sachets

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>PKU Build 10 [QH]</td>
<td>*1090.50</td>
<td>41.00</td>
<td></td>
</tr>
</tbody>
</table>

glycomacropeptide and essential amino acids with vitamins and minerals containing 20 g of protein equivalent powder for oral liquid, 30 x 32 g sachets

<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>PKU Build 20 [QH]</td>
<td>*2100.54</td>
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</table>

GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE

Restricted benefit
Phenylketonuria

glycomacropeptide formula with docosahexaenoic acid and low phenylalanine powder for oral liquid, 30 x 35 g sachets

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>PKU Sphere20 [VF]</td>
<td>*2100.54</td>
<td>41.00</td>
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</tr>
</tbody>
</table>

GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE

Note This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.

Restricted benefit
Phenylketonuria

glycomacropeptide formula with docosahexaenoic acid and low phenylalanine oral liquid, 18 x 250 mL cartons

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>PKU GMPro LQ [SB]</td>
<td>*1595.44</td>
<td>41.00</td>
<td></td>
</tr>
</tbody>
</table>

HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

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.

Keyo should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral semisolid, 48 x 100 g tubs

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keyo [VF]</td>
<td>*793.38</td>
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</table>

HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

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.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid, 32 x 200 mL cartons

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>KetoCal 4:1 LQ [SB]</td>
<td>*947.49</td>
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</table>
### HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

#### Restricted benefit
- Ketogenic diet

**Clinical criteria:**
- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 3:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

#### High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) powder for oral liquid, 300 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>24</td>
<td>5</td>
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<td>*995.82</td>
<td>41.00</td>
<td>KetoCal 3:1 [SB]</td>
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</table>

### HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

**Note** Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

#### 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.

#### High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) powder for oral liquid, 300 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>24</td>
<td>5</td>
<td>..</td>
<td>*995.82</td>
<td>41.00</td>
<td>KetoCal 4:1 [SB]</td>
</tr>
</tbody>
</table>

### ISOLEUCINE WITH CARBOHYDRATE

#### Restricted benefit
- Maple syrup urine disease

#### 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>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*490.90</td>
<td>41.00</td>
<td>Isoleucine 1000 [VF]</td>
</tr>
</tbody>
</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>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*446.94</td>
<td>41.00</td>
<td>Isoleucine 50 [VF]</td>
</tr>
</tbody>
</table>

### MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE

#### 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; OR
- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

#### Milk protein and fat formula with vitamins and minerals carbohydrate free powder for oral liquid, 225 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>
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<td>*533.34</td>
<td>41.00</td>
<td>Carbohydrate Free Mixture [SB]</td>
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</table>

### PHENYLALANINE WITH CARBOHYDRATE

#### Restricted benefit
- 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>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*446.94</td>
<td>41.00</td>
<td>Phenylalanine 50 [VF]</td>
</tr>
</tbody>
</table>
### PROTEIN FORMULA WITH AMINO ACIDS, CARBOHYDRATES, VITAMINS AND MINERALS WITHOUT PHENYLALANINE, AND SUPPLEMENTED WITH DOCSAHEXAENOIC ACID

**Restricted benefit**

**Phenylketonuria**

Protein formula with amino acids, carbohydrates, vitamins and minerals without phenylalanine, and supplemented with docosahexaenoic acid oral liquid, 30 x 130 mL pouches

<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>10658Y</td>
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<td>5</td>
<td>..</td>
<td>1934.54</td>
<td>PKU Easy [OH]</td>
</tr>
</tbody>
</table>

### PROTEIN FORMULA WITH VITAMINS AND MINERALS, AND LOW IN POTASSIUM, PHOSPHORUS, CALCIUM, CHLORIDE AND VITAMIN A

**Authority required (STREAMLINED)**

11070

**Chronic renal failure**

**Population criteria:**
- Patient must be a child aged 3 years or older.

**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.

Protein formula with vitamins and minerals, and low in potassium, phosphorus, calcium, chloride and vitamin A oral liquid, 24 x 125 mL bottles

<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>12191P</td>
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<td>5</td>
<td>..</td>
<td>1344.62</td>
<td>Renastep [VF]</td>
</tr>
</tbody>
</table>

### SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE

**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; OR
- Patient must be an infant or young child with glucose-galactose intolerance and multiple monosaccharide intolerance.

Soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 384 mL can

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
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<td>551.34</td>
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</tbody>
</table>

### 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>
<th>MRVSN $</th>
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<tr>
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<td>5</td>
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<td>158.34</td>
<td>Sno-Pro [SB]</td>
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</table>

Triglycerides long chain with glucose polymer oral liquid, 6 x 1 L cartons

<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>5</td>
<td>..</td>
<td>258.02</td>
<td>ProZero [VF]</td>
</tr>
</tbody>
</table>

Triglycerides long chain with glucose polymer 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>
<th>Brand Name and Manufacturer</th>
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<tr>
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<td>290.16</td>
<td>ProZero [VF]</td>
</tr>
</tbody>
</table>

### TRIGLYCERIDES MEDIUM CHAIN AND 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 medium chain and long chain with glucose polymer powder for oral liquid, 400 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>238.30</td>
<td>Duocal [SB]</td>
</tr>
</tbody>
</table>
- **TRIGLYCERIDES MEDIUM CHAIN FORMULA**

  **Note** No increase in the maximum quantity or number of units may be authorised.

  **Note** No increase in the maximum number of repeats may be authorised.

  **Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

  Authority required (STREAMLINED)
  
  **6165**
  Chylous ascites

  Authority required (STREAMLINED)
  
  **6192**
  Chylothorax

  Authority required (STREAMLINED)
  
  **6173**
  Fat malabsorption

  **Clinical criteria:**
  
  - The condition must be due to liver disease; OR
  - The condition must be due to short gut syndrome; OR
  - The condition must be due to cystic fibrosis; OR
  - The condition must be due to gastrointestinal disorders.

  Authority required (STREAMLINED)
  
  **6156**
  Hyperlipoproteinaemia type 1

  Authority required (STREAMLINED)
  
  **6136**
  Long chain fatty acid oxidation disorders

  **triglycerides medium chain formula powder for oral liquid, 30 x 16 g sachets**
  
  **9383W**
  Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
  --- | --- | --- | --- | --- | ---
  4 | 5 | .. | *202.54 | 41.00 | MCT Pro-Cal [VF]

- **TYROSINE WITH CARBOHYDRATE**

  **Note** This formulation is suitable for patients aged 3 and older.

  Restricted benefit
  
  Phenylketonuria

  **tyrosine with carbohydrate containing 1 g tyrosine oral liquid: powder for, 30 x 4 g sachets**
  
  **9165J**
  Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
  --- | --- | --- | --- | --- | ---
  4 | 5 | .. | *446.94 | 41.00 | Tyrosine 1000 [VF]

- **VALINE WITH CARBOHYDRATE**

  Restricted benefit
  
  Maple syrup urine disease

  **valine with carbohydrate containing 1 g valine oral liquid: powder for, 30 x 4 g sachets**
  
  **9434M**
  Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
  --- | --- | --- | --- | --- | ---
  4 | 5 | .. | *490.90 | 41.00 | Valine 1000 [VF]

  **valine with carbohydrate containing 50 mg valine oral liquid: powder for, 30 x 4 g sachets**
  
  **9135T**
  Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
  --- | --- | --- | --- | --- | ---
  4 | 5 | .. | *446.94 | 41.00 | Valine 50 [VF]

- **VITAMINS, MINERALS AND TRACE ELEMENTS**

  **Note** Phlexy-Vits must only be used under strict supervision of a dietician and a paediatrician.

  Restricted benefit
  
  Dietary management of conditions requiring a highly restrictive therapeutic diet

  **Clinical criteria:**
  
  - Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, AND
  - Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

  **Population criteria:**
  
  - Patient must be aged 3 years or older.

  **vitamins, minerals and trace elements powder for oral liquid, 30 x 7 g sachets**
  
  **11200L**
  Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
  --- | --- | --- | --- | --- | ---
  1 | 5 | .. | 280.83 | 41.00 | Phlexy-Vits [SB]
**VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE**

**Note** FruitiVits must only be used under strict supervision of a dietitian and a paediatrician.

---

**Restricted benefit**

Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**

- Patient must be aged 3 years or older.

vitasms, minerals and trace elements with carbohydrate powder for oral liquid, 30 x 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>
</tr>
</thead>
<tbody>
<tr>
<td>10149E</td>
<td>5</td>
<td>..</td>
<td>253.44</td>
<td>41.00</td>
<td>FruitiVits [VF]</td>
</tr>
</tbody>
</table>

---

**VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE**

**Note** Paediatric Seravit must only be used under strict supervision of a dietitian and a paediatrician.

---

**Restricted benefit**

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.

vitasms, minerals and trace elements with carbohydrate powder for oral liquid, 200 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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<td>..</td>
<td>*335.58</td>
<td>41.00</td>
<td>Paediatric Seravit [SB]</td>
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---

**WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**

**Authority required (STREAMLINED)**

6190

Chronic renal failure

**Population criteria:**

- Patient must be an infant or a young child.

**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.

whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphatse, potassium and lactose powder for oral liquid, 6 x 400 g cans

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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**WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**

**Authority required (STREAMLINED)**

6190

Chronic renal failure

**Population criteria:**

- Patient must be an infant or a young child.

**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.

whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphatse, potassium and lactose powder for oral liquid, 400 g

<table>
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# Palliative Care

## ALIMENTARY TRACT AND METABOLISM

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
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<td>STOMATOLOGICAL PREPARATIONS</td>
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<tr>
<td>DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS</td>
<td>981</td>
</tr>
<tr>
<td>BELTADONNA AND DERIVATIVES, PLAIN</td>
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<td>PROPULSIVES</td>
<td>981</td>
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<td>DRUGS FOR CONSTIPATION</td>
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</tbody>
</table>

## MUSCULO-SKELETAL SYSTEM

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<td>ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS</td>
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<tr>
<td>ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS</td>
<td>983</td>
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## NERVOUS SYSTEM

<table>
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<tr>
<td>ANALGESICS</td>
<td>984</td>
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<tr>
<td>OPIOIDS</td>
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</tr>
<tr>
<td>OTHER ANALGESICS AND ANTIPYRETICS</td>
<td>990</td>
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<td>ANXIOLYTICS</td>
<td>991</td>
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<tr>
<td>HYPNOTICS AND SEDATIVES</td>
<td>992</td>
</tr>
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</table>
ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

**STOMATOLOGICAL PREPARATIONS**

*Other agents for local oral treatment*

**BENZYMADINE**

*Authority required (STREAMLINED)*

**6197**

Painful mouth

**Clinical criteria:**

- Patient must be receiving palliative care.

**benzydamine hydrochloride 0.15% mouthwash, 500 mL**

5385K

<table>
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<tr>
<th>Max Qty Packs</th>
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**DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS**

**BELLADONNA AND DERIVATIVES, PLAIN**

*Belladonna alkaloids, semisynthetic, quaternary ammonium compounds*

**HYOSCINE BUTYLBROMIDE**

*Authority required (STREAMLINED)*

**6207**

For use in patients receiving palliative care

**hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules**

5317W

<table>
<thead>
<tr>
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<td>6</td>
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<td>76.68</td>
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<td>* Buscopan [VZ]</td>
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<td></td>
<td>* HYOSCINE BUTYLBROMIDE SXP [XC]</td>
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**PROPULSIVES**

*Propulsives*

**METOCLOPRAMIDE**

*Authority required (STREAMLINED)*

**6084**

Nausea or gastric stasis

**Clinical criteria:**

- Patient must be receiving palliative care.

**metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules**

10762K

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<tr>
<td>4</td>
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<td>34.86</td>
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**DRUGS FOR CONSTIPATION**

**DRUGS FOR CONSTIPATION**

*Contact laxatives*

**BISACODYL**

*Restricted benefit*

Constipation

**Clinical criteria:**

- Patient must be receiving palliative care.

**bisacodyl 10 mg suppository, 10**

5303D

<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>24.66</td>
<td>25.95</td>
<td>* Petrus Bisacodyl Suppositories [PP]</td>
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<td></td>
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<td></td>
<td>1.29</td>
<td>25.95</td>
<td>* Dulcolax [VZ]</td>
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**bisacodyl 10 mg suppository, 12**

5304E

<table>
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<tr>
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<tr>
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<td>22.38</td>
<td>23.67</td>
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</table>
### Palliative Care

**Bisacodyl**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bisalax [AS]</td>
<td>39.43</td>
<td>40.72</td>
<td></td>
</tr>
</tbody>
</table>

**Rhamnus Frangula + Sterculia**

#### Restricted benefit

**Constipation**

Clinical criteria:
- Patient must be receiving palliative care.

<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>Normacol Plus [NE]</td>
<td>26.12</td>
<td>27.41</td>
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**Macrogol**

#### Authority required (STREAMLINED)

**Constipation**

Clinical criteria:
- Patient must be receiving palliative care.

**Macrogol-3350 + Sodium Chloride + Bicarbonate + Potassium Chloride**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
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<td>OsmoLax [KY]</td>
<td>22.10</td>
<td>23.39</td>
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**Macrogol-3350 + Enemas**

Clinical criteria:
- Patient must be receiving palliative care.

<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>Bsalax [AS]</td>
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<td>40.72</td>
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### Osmotically Acting Laxatives

**Bisacodyl**

#### Restricted benefit

**Constipation**

Clinical criteria:
- Patient must be receiving palliative care.

<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>Lax-Tab [AE]</td>
<td>18.01</td>
<td>19.30</td>
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### Enemas

**Citric Acid + Lauryl Sulfocacetate Sodium + Sorbitol**

#### Restricted benefit

**Constipation**

Clinical criteria:
- Patient must be receiving palliative care.
sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 12 x 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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<th>Brand Name and Manufacturer</th>
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<tr>
<td>5331N</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*30.28</td>
<td>35.77 Micolette [AE]</td>
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</table>

Peripheral opioid receptor antagonists

**METHYLNALEXONE**

Authority required (STREAMLINED)

**6180**

Opioid-induced constipation

Clinical criteria:
- The treatment must be in combination with oral laxatives, **AND**
- Patient must be receiving palliative care, **AND**
- Patient must have failed to respond to laxatives.

methylnalexone bromide 12 mg/0.6 mL injection, 0.6 mL vial

<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>5423K</td>
<td>7</td>
<td>..</td>
<td>..</td>
<td>243.57</td>
<td>41.00 Relistor [LM]</td>
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</table>

methylnalexone bromide 12 mg/0.6 mL injection, 7 x 0.6 mL vials

<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>5424L</td>
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<td>243.55</td>
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**MUSCULO-SKELETAL SYSTEM**

**ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS**

**ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS**

Acetic acid derivatives and related substances

**DICLOFENAC**

Restricted benefit

Severe pain

Clinical criteria:
- Patient must be receiving palliative care.

diclofenac sodium 50 mg enteric tablet, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>14.07</td>
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<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>* Clonac 50 [RW]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Diclofen Amneal [ED]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Diclofen Sandoz [SZ]</td>
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<td>APO-Diclofen AN [EA]</td>
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<td></td>
<td></td>
<td></td>
<td>* Fenac [AF]</td>
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<td></td>
<td></td>
<td></td>
<td>Voltaren 50 [NV]</td>
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<td></td>
<td></td>
<td>Voltaren 100 [NV]</td>
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<td>*3.46</td>
<td>17.53 Voltaren 50 [NV]</td>
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<td>15.36</td>
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diclofenac sodium 100 mg suppository, 20

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<td>5363G</td>
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diclofenac sodium 25 mg enteric tablet, 50

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<td></td>
<td></td>
<td></td>
<td>* Clonac 25 [RW]</td>
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<td>* Diclofen Amneal [ED]</td>
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<td></td>
<td>* Diclofen Sandoz [SZ]</td>
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<td></td>
<td>* Diclofen AN [EA]</td>
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<td>* Fenac [AF]</td>
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<td>*18.40 Voltaren 25 [NV]</td>
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<td>16.25</td>
<td>Voltaren 25 [NV]</td>
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**INDOMETACIN**

Restricted benefit

Severe pain

Clinical criteria:
- Patient must be receiving palliative care.

indometacin 25 mg capsule, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td></td>
<td>* Diclofen Sandoz [SZ]</td>
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<td>*4.04</td>
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<td>Indocid [AS]</td>
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indometacin 100 mg suppository, 20

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<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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<td>5378C</td>
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<td>..</td>
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Propionic acid derivatives
### IBUPROFEN

**Restricted benefit**

Severe pain

**Clinical criteria:**
- Patient must be receiving palliative care.

#### ibuprofen 400 mg tablet, 30

<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>3</td>
<td>3</td>
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<td>*17.79</td>
<td>19.08</td>
<td>APO-Ibuprofen 400 [TX]</td>
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<td>9</td>
<td>9</td>
<td>*26.79</td>
<td>19.08</td>
<td>Brufen [GO]</td>
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</tr>
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</table>

### NAPROXEN

**Restricted benefit**

Severe pain

**Treatment criteria:**
- Patient must be undergoing palliative care.

**Clinical criteria:**
- 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

<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>3</td>
<td>..</td>
<td>122.71</td>
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<td>Phebra Naproxen Suspension  [FF]</td>
</tr>
</tbody>
</table>

#### naproxen 1 g modified release tablet, 28

<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>
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<tr>
<td>1</td>
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<td>..</td>
<td>18.58</td>
<td>19.87</td>
<td>Proxen SR 1000 [IX]</td>
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<tr>
<td>‡1.12</td>
<td>1.12</td>
<td>19.70</td>
<td>19.87</td>
<td>Naprosyn SR1000 [IX]</td>
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</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>2</td>
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<td>*19.28</td>
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</table>

#### naproxen 500 mg tablet, 50

<table>
<thead>
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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>3</td>
<td>..</td>
<td>17.39</td>
<td>18.68</td>
<td>Naprosyn [IX]</td>
</tr>
</tbody>
</table>

#### naproxen 750 mg modified release 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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<tbody>
<tr>
<td>1</td>
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<td>16.94</td>
<td>18.23</td>
<td>Proxen SR 750 [IX]</td>
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<tr>
<td>‡1.06</td>
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<td>Naprosyn SR750 [IX]</td>
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</table>

### NAPROXEN

**Note** 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>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>..</td>
<td>17.54</td>
<td>18.83</td>
<td>Crysanal [IX]</td>
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<tr>
<td>‡1.89</td>
<td>1.89</td>
<td>19.43</td>
<td>18.83</td>
<td>Anaprox 550 [IX]</td>
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</tr>
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</table>

### NERVOUS SYSTEM

#### ANALGESICS

#### OPIOIDS

Natural opium alkaloids

### MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Telephone approvals are limited to 1 month’s therapy.
Palliative Care

### NERVOUS SYSTEM

**Palliative Authority required**
Chronic severe disabling pain

**Clinical criteria:**
- Patient must be receiving palliative care, AND
- The condition must be unresponsive to non-opioid analgesics.

<table>
<thead>
<tr>
<th>morphine sulfate pentahydrate 200 mg modified release tablet, 28</th>
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</thead>
<tbody>
<tr>
<td><strong>5391R</strong> Max.Qty Packs</td>
</tr>
<tr>
<td>-------------------------</td>
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</tr>
</tbody>
</table>

**MORPHINE**

**Caution** The risk of drug dependence is high.

**Note** Telephone approvals are limited to 1 month's therapy.

**Clinical criteria:**
- Patient must be receiving palliative care, AND
- The condition must be unresponsive to non-opioid analgesics.

<table>
<thead>
<tr>
<th>morphine sulfate pentahydrate 10 mg tablet, 20</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5393W</strong> Max.Qty Packs</td>
</tr>
<tr>
<td>-------------------------</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>morphine sulfate pentahydrate 20 mg tablet, 20</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5394X</strong> Max.Qty Packs</td>
</tr>
<tr>
<td>-------------------------</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

**MORPHINE**

**Caution** The risk of drug dependence is high.

Morphone sulfate pentahydrate 10 and 20 mg modified release capsules must not be co-prescribed with immediate release oral morphine, when it has been prescribed for the reduction of chronic breathlessness.

**Note** Treatment should be initiated by a specialist knowledgeable in the use of potent opioids for the management of chronic breathlessness.

**Note** Applications for an increased maximum quantity to provide for 1 month's supply of this drug will be authorised.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note** Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Restricted benefit**
Chronic Breathlessness

**Clinical criteria:**
- Patient must be receiving palliative care.

<table>
<thead>
<tr>
<th>morphine sulfate pentahydrate 10 mg modified release capsule, 28</th>
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<tbody>
<tr>
<td><strong>11760Y</strong> Max.Qty Packs</td>
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<tr>
<td>--------------------------</td>
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<tr>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>morphine sulfate pentahydrate 20 mg modified release capsule, 28</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>11761B</strong> Max.Qty Packs</td>
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<tr>
<td>--------------------------</td>
</tr>
<tr>
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</table>

**Phenylpiperidine derivatives**

**FENTANYL**

**Caution** The risk of drug dependence is high.

**Note** Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Breakthrough pain

**Clinical criteria:**
- Patient must have cancer, AND
- Patient must have pain directly attributable to cancer, AND
• Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
• Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; **OR**
• The treatment must be used as short acting opioids are considered clinically inappropriate; **OR**
• Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**
• Patient must be undergoing palliative care.

**FENTANYL**

**Caution** The risk of drug dependence is high.

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** No increase in the maximum number of repeats may be authorised.

**Authority required**
Breakthrough pain
Treatment Phase: Initial treatment for dose titration

**Clinical criteria:**
• Patient must have cancer, **AND**
• Patient must have pain directly attributable to cancer, **AND**
• Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
• Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
• The treatment must be used as short acting opioids are considered clinically inappropriate; OR
• Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**
• Patient must be undergoing palliative care.

<table>
<thead>
<tr>
<th>Fentanyl 600 microgram orally disintegrating tablet, 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>10722H</td>
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</table>

<table>
<thead>
<tr>
<th>Fentanyl 800 microgram orally disintegrating tablet, 4</th>
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</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
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<tr>
<td>-------------------</td>
</tr>
<tr>
<td>10723J</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fentanyl 100 microgram orally disintegrating tablet, 4</th>
</tr>
</thead>
<tbody>
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<td><strong>Max Qty Packs</strong></td>
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<table>
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<th>Fentanyl 200 microgram orally disintegrating tablet, 4</th>
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</tr>
<tr>
<td>10697B</td>
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<table>
<thead>
<tr>
<th>Fentanyl 400 microgram orally disintegrating tablet, 4</th>
</tr>
</thead>
<tbody>
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<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>10739F</td>
</tr>
</tbody>
</table>

**FENTANYL**

**Caution:** The risk of drug dependence is high.

**Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note:** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months’ supply may be authorised.

**Note:** Telephone approvals are limited to 1 month's therapy.

**Authority required**

**Breakthrough pain**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
• Patient must have cancer, **AND**
• Patient must have pain directly attributable to cancer, **AND**
• Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
• The treatment must be used as short acting opioids are considered clinically inappropriate; OR
• The treatment must be used as short acting opioids are considered clinically inappropriate; OR
• Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**
• Patient must be undergoing palliative care.

<table>
<thead>
<tr>
<th>Fentanyl 1200 microgram lozenge, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>5411T</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Fentanyl 1600 microgram lozenge, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>5412W</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Fentanyl 200 microgram lozenge, 30</th>
</tr>
</thead>
<tbody>
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<tr>
<td>-------------------</td>
</tr>
<tr>
<td>5407N</td>
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<table>
<thead>
<tr>
<th>Fentanyl 400 microgram lozenge, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>5408P</td>
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</table>
**FENTANYL**

**Caution** The risk of drug dependence is high.

**Note Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Note** For first continuing supply, applications for increased repeats for up to 3 months’ supply may be authorised.

**Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months’ supply may be authorised.

**Note** Telephone approvals are limited to 1 months’ therapy.

**Authority required**
Breakthrough pain
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have cancer, **AND**
- Patient must have pain directly attributable to cancer, **AND**
- Patient must be assessed as receiving adequate management of their persistent pain with opioids, **AND**
- Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
- The treatment must be used as short acting opioids are considered clinically inappropriate; OR
- Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

**Treatment criteria:**
- Patient must be undergoing palliative care.
NERVOUS SYSTEM

Palliative Care

fentanyl 800 microgram orally disintegrating 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>2</td>
<td></td>
<td>*441.74</td>
<td>41.00</td>
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<td>Fentora [TB]</td>
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</table>

fentanyl 100 microgram orally disintegrating 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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<tbody>
<tr>
<td>2</td>
<td></td>
<td>*441.74</td>
<td>41.00</td>
<td></td>
<td>Fentora [TB]</td>
</tr>
</tbody>
</table>

Diphenylpropylamine derivatives

- **METHADONE**
  - **Caution** The risk of drug dependence is high.
  - **Note** Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.
  - **Note** Telephone approvals are limited to 1 month's therapy.
  - **Note** Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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-opioid analgesics.

methadone hydrochloride 5 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>1</td>
<td>2</td>
<td>25.32</td>
<td>26.61</td>
<td></td>
<td>Aspen Methadone Syrup [AS]</td>
</tr>
</tbody>
</table>

methadone hydrochloride 5 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>1</td>
<td></td>
<td>25.32</td>
<td>26.61</td>
<td></td>
<td>Aspen Methadone Syrup [AS]</td>
</tr>
</tbody>
</table>

Oripavine derivatives

- **BUPRENORPHINE**
  - **Caution** The risk of drug dependence is high.
  - **Note** Telephone approvals are limited to 1 month's therapy.

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-opioid analgesics.

buprenorphine 5 microgram/hour patch, 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>
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<tbody>
<tr>
<td>2</td>
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<td>*41.20</td>
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<td>Buprenorphine Sandoz [SZ]</td>
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</table>

buprenorphine 15 microgram/hour patch, 2

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>*72.64</td>
<td>41.00</td>
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<td>Buprenorphine Sandoz [SZ]</td>
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</tbody>
</table>
NERVOUS SYSTEM

Palliative

**Schedule of Pharmaceutical Benefits – December 2020**

**NERVOUS SYSTEM**

### PARACETAMOL

**Restricted benefit**

Analgesia or fever

**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 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>4</td>
<td>3</td>
<td>82.98</td>
<td>41.00</td>
<td></td>
<td>Panadol [GC]</td>
</tr>
</tbody>
</table>

**Note**

Pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 96 and pharmaceutical benefits that have the form paracetamol 665 mg tablet: modified release, 192 are equivalent for the purposes of substitution.

#### paracetamol 500 mg suppository, 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>
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<tbody>
<tr>
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<td>3</td>
<td>97.04</td>
<td>41.00</td>
<td></td>
<td>Panadol [GC]</td>
</tr>
</tbody>
</table>

**ANTIEPILEPTICS**

**Benzodiazepine derivatives**

#### CLONAZEPAM

**Note**

No increase in the maximum number of repeats may be authorised.

**Authority required**
Myoclonus

Clinical criteria:
- The treatment must be for prophylaxis or prevention of the indication, AND
- Patient must be receiving palliative care.

clonazepam 2.5 mg/mL (0.1 mg/drop) oral liquid, 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>2</td>
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<td>..</td>
<td>19.52</td>
<td>20.81</td>
<td>Rivtiril [RO]</td>
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</table>

clonazepam 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>1</td>
<td>3</td>
<td>..</td>
<td>22.73</td>
<td>24.02</td>
<td>Paxam 2 [AF]</td>
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</table>

**CLONAZEPAM**

Note: Pharmaceutical benefits that have form pack size clonazepam 500 microgram tablet, 100 and clonazepam 500 microgram tablet, 50 are equivalent for the purposes of substitution.

Note: No increase in the maximum number of repeats may be authorised.

**ANXIOLYTICS**

**Benzodiazepine derivatives**

**DIAZEPAM**

Note: No increase in the maximum number of repeats may be authorised.

**OXAZEPAM**

Note: No increase in the maximum number of repeats may be authorised.
NERVOUS SYSTEM

HYPNOTICS AND SEDATIVES

Benzodiazepine derivatives

- NITRAZEPAM
  
  Note: No increase in the maximum number of repeats may be authorised.

  Authority required
  Insomnia
  Clinical criteria:
  - Patient must be receiving palliative care.

  nitrazepam 5 mg tablet, 25
  5359C

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>3</td>
<td>*15.24</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mogadon [IL]</td>
</tr>
</tbody>
</table>

- TEMAZEPAM
  
  Note: No increase in the maximum number of repeats may be authorised.

  Authority required
  Insomnia
  Clinical criteria:
  - Patient must be receiving palliative care.

  temazepam 10 mg tablet, 25
  5375X

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tr>
<td></td>
<td></td>
<td>APO-Temazepam [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>* Temaze [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>* Temtabs [LN]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>* Normison [AS]</td>
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</table>

  *PREMIUM SAVING = 15.47
  *MRVSN SAVING = 15.47
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 Schedule (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 prescription. 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.

<table>
<thead>
<tr>
<th>(A) Covering</th>
<th>(B) Absorbing</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Film;</td>
<td>Foam (Light Exudate);</td>
<td>Hydrocolloid (Superficial Wound—Light Exudate)</td>
</tr>
<tr>
<td>Film Island</td>
<td>Hydroactive (Superficial Wound—Light Exudate)</td>
<td></td>
</tr>
<tr>
<td>Gauze—Paraffin;</td>
<td>Hydrocolloid (Superficial Wound—Light Exudate)</td>
<td></td>
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<tr>
<td>Non-adherent</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Red Granulating Wound**

Aims: (1) to protect the granulating tissue; (2) to encourage epithelialisation; (3) to absorb excess exudate.

<table>
<thead>
<tr>
<th>LIGHT EXUDATE:</th>
<th>Superficial</th>
<th>Cavity</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Absorbing</td>
<td>Foam (Light Exudate);</td>
<td>Hydrocolloid (Cavity Wound)</td>
</tr>
<tr>
<td></td>
<td>Hydroactive (Superficial Wound—Light Exudate);</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hydrocolloid (Superficial Wound—Light Exudate)</td>
<td></td>
</tr>
<tr>
<td>(B) Moisture donating</td>
<td>Hydrogel—Amorphous;</td>
<td>Hydrogel—Amorphous</td>
</tr>
<tr>
<td></td>
<td>Hydrogel—Sheet</td>
<td></td>
</tr>
</tbody>
</table>

**Yellow Sloughy Wound**

Aims: (1) to remove slough; (2) to encourage granulation; (3) to absorb excess exudate.

<table>
<thead>
<tr>
<th>LIGHT EXUDATE:</th>
<th>Superficial</th>
<th>Cavity</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Absorbing</td>
<td>Cadexomer Iodine;</td>
<td>Hydrocolloid (Cavity Wound)</td>
</tr>
<tr>
<td></td>
<td>Foam—Light Exudate;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Foam with Charcoal;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hydroactive (Superficial Wound—Moderate Exudate);</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hydrocolloid (Superficial Wound—Moderate Exudate)</td>
<td></td>
</tr>
<tr>
<td>(B) Moisture Donating</td>
<td>Hydrogel—Amorphous;</td>
<td>Hydrogel—Amorphous</td>
</tr>
<tr>
<td></td>
<td>Hydrogel—Sheet</td>
<td></td>
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</table>

**HIGH EXUDATE:**

<table>
<thead>
<tr>
<th>Superficial</th>
<th>Cavity</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Absorbing</td>
<td>Alginate (Superficial Wound);</td>
</tr>
<tr>
<td></td>
<td>Foam—Heavy Exudate;</td>
</tr>
<tr>
<td></td>
<td>Hydroactive (Superficial Wound—Moderate Exudate);</td>
</tr>
<tr>
<td></td>
<td>Hydrocolloid (Superficial Wound—Moderate/High Exudate)</td>
</tr>
<tr>
<td></td>
<td>Hydrocolloid (Cavity Wound)</td>
</tr>
<tr>
<td>(B) Moisture donating</td>
<td>Hydrogel—Amorphous;</td>
</tr>
<tr>
<td></td>
<td>Hydrogel—Sheet</td>
</tr>
</tbody>
</table>

**NOT APPROPRIATE**

Repatriation Pharmaceutical Benefits Scheme 997
Black Necrotic Wound
Aims: To remove eschar by — (1) sharp debridement, e.g., scissor/scalpel and/or (2) rehydration and autolytic debridement. (These wounds usually produce a LIGHT EXUDATE.)

<table>
<thead>
<tr>
<th>DRY / LIGHT EXUDATE:</th>
<th>Superficial</th>
<th>Cavity</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Absorbing</td>
<td>• Hydroactive (Superficial Wound—Light Exudate); • Hydrocolloid (Superficial Wound—Light/Moderate Exudate)</td>
<td>• Hydrocolloid (Cavity Wound)</td>
</tr>
<tr>
<td>(B) Moisture donating</td>
<td>• Hydrogel—Amorphous; • Hydrogel—Sheet</td>
<td>• Hydrogel—Amorphous; • Hydrogel—Sheet</td>
</tr>
</tbody>
</table>

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 Products
Ordering Coloplast Products
Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

Ordering 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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<tr>
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<tr>
<td>All other therapeutic products</td>
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<td>General nutrients</td>
<td>1025</td>
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<tr>
<td>Other nutrients</td>
<td>1025</td>
</tr>
<tr>
<td>All other non-therapeutic products</td>
<td>1025</td>
</tr>
<tr>
<td>All other non-therapeutic products</td>
<td>1025</td>
</tr>
</tbody>
</table>
### ALIMENTARY TRACT AND METABOLISM

#### STOMATOLOGICAL PREPARATIONS

**Antiinfectives and antiseptics for oral treatment**

#### CHLORHEXIDINE

- **chlorhexidine gluconate 0.2% mouthwash, 250 mL**
  - 4161B
  - Max.Qty Packs: 1
  - No. of Rpts: ..
  - Premium $: 16.78
  - DPMQ $: 6.60
  - MRVSN $: 6.60
  - Brand Name and Manufacturer: Plaqacide [OB]

- **chlorhexidine gluconate 0.2% mouthwash, 300 mL**
  - 4204G
  - Max.Qty Packs: 1
  - No. of Rpts: ..
  - Premium $: 19.72
  - DPMQ $: 6.60
  - MRVSN $: 6.60
  - Brand Name and Manufacturer: Savacol Mouth and Throat Rinse [OM]

#### NYSTATIN

- **nystatin 100 000 units/mL oral liquid, 24 mL**
  - 10854G
  - Max.Qty Packs: 1
  - No. of Rpts: 1
  - Premium $: 18.50
  - DPMQ $: 6.60
  - MRVSN $: 6.60
  - Brand Name and Manufacturer: Pharmacy Action Nystatin Oral Drops [TX]
  - * Brand Name and Manufacturer: Trust Nystatin Oral Drops [CR]
  - * Brand Name and Manufacturer: Mycostatin Oral Drops [LN]

#### DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

**Synthetic anticholinergics, esters with tertiary amino group**

#### MEBEVERINE

- **mebeverine hydrochloride 135 mg tablet, 90**
  - 4328T
  - Max.Qty Packs: 1
  - No. of Rpts: ..
  - Premium $: 29.84
  - DPMQ $: 6.60
  - MRVSN $: 6.60
  - Brand Name and Manufacturer: APO-Mebeverine [TX]
  - * Brand Name and Manufacturer: Colofac [GO]
  - * Brand Name and Manufacturer: Colese [AF]

#### BELLADONNA AND DERIVATIVES, PLAIN

**Belladonna alkaloids, semisynthetic, quaternary ammonium compounds**

#### HYOSCINE BUTYLBROMIDE

- **hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules**
  - 4279F
  - Max.Qty Packs: 1
  - No. of Rpts: ..
  - Premium $: 22.80
  - DPMQ $: 6.60
  - MRVSN $: 6.60
  - Brand Name and Manufacturer: Buscopan [VZ]
  - * Brand Name and Manufacturer: HYOSCINE BUTYLBROMIDE SXP [XC]

#### DRUGS FOR CONSTIPATION

**Softeners, emollients**

#### DOCUSATE

- **docusate sodium 50 mg tablet, 100**
  - 4200C
  - Max.Qty Packs: 1
  - No. of Rpts: 2
  - Premium $: 18.88
  - DPMQ $: 6.60
  - MRVSN $: 6.60
  - Brand Name and Manufacturer: Coloxyl 50 [AS]

**Contact laxatives**

#### BISACODYL

- **bisacodyl 10 mg suppository, 10**
  - 10578R
  - Max.Qty Packs: 3
  - No. of Rpts: 5
  - Premium $: 24.66
  - DPMQ $: 6.60
  - MRVSN $: 6.60
  - Brand Name and Manufacturer: Petrus Bisacodyl Suppositories [PP]
  - * Brand Name and Manufacturer: Bisacodyl [PP]

- **bisacodyl 10 mg suppository, 12**
  - 10580W
  - Max.Qty Packs: 3
  - No. of Rpts: 4
  - Premium $: 22.38
  - DPMQ $: 6.60
  - MRVSN $: 6.60
  - Brand Name and Manufacturer: Petrus Bisacodyl Suppositories [PP]
### Alimentary Tract and Metabolism

**Repatriation Pharmaceutical Benefits Scheme**

**DOCUSATE + SENNOSIDE B**

<table>
<thead>
<tr>
<th>Docusate sodium 50 mg + sennoside B 8 mg tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>---------------</td>
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<td>1</td>
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**SENNOSIDE B**

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<thead>
<tr>
<th>Sennoside B 7.5 mg tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>---------------</td>
</tr>
<tr>
<td>1</td>
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<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Dry Psyllium Husk**

<table>
<thead>
<tr>
<th>Dry psyllium husk 3.5 g powder for oral liquid, 30 sachets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>---------------</td>
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<tr>
<td>‡1</td>
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</tbody>
</table>

**Psyllium Husk Powder**

<table>
<thead>
<tr>
<th>Psyllium husk powder 3.4 g/7 g powder for oral liquid, 336 g</th>
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<tbody>
<tr>
<td>Max Qty Packs</td>
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</table>

<table>
<thead>
<tr>
<th>Psyllium husk powder 3.4 g/5.9 g powder for oral liquid, 283 g</th>
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<tr>
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**Rhamnus Frangula + Sterculia**

<table>
<thead>
<tr>
<th>Rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
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<tr>
<td>‡1</td>
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</tbody>
</table>

**Citric Acid + Lauryl Sulfoacetate Sodium + Sorbitol**

<table>
<thead>
<tr>
<th>Sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 4 x 5 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
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<td>---------------</td>
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**Glycerol**

<table>
<thead>
<tr>
<th>Glycerol 1.4 g suppository, 12</th>
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<tbody>
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<td>Max Qty Packs</td>
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<tr>
<td>---------------</td>
</tr>
<tr>
<td>3</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Glycerol 2.8 g suppository, 12</th>
</tr>
</thead>
<tbody>
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<td>Max Qty Packs</td>
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<tr>
<td>3</td>
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<td></td>
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</tbody>
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<table>
<thead>
<tr>
<th>Glycerol 700 mg suppository, 12</th>
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<tbody>
<tr>
<td>Max Qty Packs</td>
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<td>---------------</td>
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<tr>
<td>3</td>
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</table>
**ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS**

**ELECTROLYTES WITH CARBOHYDRATES**

*Oral rehydration salt formulations*

**SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID**

sodium chloride 470 mg + potassium chloride 300 mg (potassium 4 mmol) + glucose monohydrate 3.56 g + sodium acid citrate 530 mg powder for oral liquid, 10 x 4.9 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>10574M</td>
<td>..</td>
<td>..</td>
<td>16.83</td>
<td>6.60</td>
<td>restore O.R.S. [EA]</td>
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</table>

**ANTIPROPULSIVES**

*Antipropulsives*

**LOPERAMIDE**

loperamide hydrochloride 2 mg capsule, 12

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<td>10592L</td>
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<td>..</td>
<td>13.51</td>
<td>6.60</td>
<td>Gastrex [CR]</td>
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loperamide hydrochloride 2 mg capsule, 20

<table>
<thead>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>11135C</td>
<td>..</td>
<td>..</td>
<td>13.51</td>
<td>6.60</td>
<td>* Gastrex [CR]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Pharmacy Action Diarrhoea Relief [GQ]</td>
</tr>
</tbody>
</table>

**ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS**

**ANALST**

Peripherally acting antiobesity products

**ORLISTAT**

*Note* The patient should be ideally enrolled in an exercise program and be receiving supplemental vitamins.

**Authority required**

Obesity

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a Body Mass Index (BMI) greater than or equal to 35 with no known co-morbidities; OR
- Patient must have a 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, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available), **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime.

The prescriber must provide the patient’s initial body weight and BMI at the time of application.

**Authority required**

Obesity

Treatment Phase: Continuing treatment (3 to 6 months following commencement)

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have reduced their initial body weight by 2.5 kg or 2.5% (whichever is the lesser) during the period 3 to 6 months following commencement of treatment with this drug, **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

**Authority required**

Obesity

Treatment Phase: Continuing treatment (6 to 12 months following commencement)

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must have reduced their initial body weight by 5 kg or 5% (whichever is the lesser) during the period 6 to 12 months following commencement of treatment with this drug, **AND**
- The treatment must not exceed 12 months in total from initial application, **AND**
- Patient must not receive more than 1 continuous treatment in a lifetime, **AND**
- Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).
orlistat 120 mg capsule, 84

<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>134.68</td>
<td>6.60</td>
<td>Xenical [PB]</td>
</tr>
</tbody>
</table>

**VITAMINS**

**VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12**

**Vitamin B1, plain**

thiamine hydrochloride 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>1</td>
<td>2</td>
<td>..</td>
<td>15.91</td>
<td>6.60</td>
<td>Betavit [PP]</td>
</tr>
</tbody>
</table>

**VITAMIN B-COMPLEX, INCL. COMBINATIONS**

**Vitamin B-complex, plain**

lysine hydrochloride 300 mg/10 mL + thiamine hydrochloride 10 mg/10 mL + pyridoxine hydrochloride 5 mg/10 mL + cyanocobalamin 25 microgram/10 mL + iron (as ferric pyrophosphate) 10 mg/10 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>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>18.04</td>
<td>6.60</td>
<td>Accomin Adult Tonic [PF]</td>
</tr>
</tbody>
</table>

**MINERAL SUPPLEMENTS**

**CALCIUM**

**Calcium**

**CALCIUM**

Restricted benefit

Hyperphosphataemia

Clinical criteria:

- The condition must be associated with chronic renal failure.

calcium carbonate 1.5 g (calcium 600 mg) tablet, 120

<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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</thead>
<tbody>
<tr>
<td>2</td>
<td>1</td>
<td>..</td>
<td>*23.16</td>
<td>6.60</td>
<td>* CAL-600 [PP]</td>
<td>* Cal-care 600 mg [CR]</td>
</tr>
</tbody>
</table>

calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120

<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>
<td>1</td>
<td>..</td>
<td>*27.88</td>
<td>6.60</td>
<td>Cal-500 [PP]</td>
</tr>
</tbody>
</table>

**CALCIUM**

Restricted benefit

Hypocalcaemia

Restricted benefit

Osteoporosis

Restricted benefit

Proven calcium malabsorption

calcium carbonate 1.5 g (calcium 600 mg) tablet, 120

<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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</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>17.59</td>
<td>6.60</td>
<td>* CAL-600 [PP]</td>
<td>* Cal-care 600 mg [CR]</td>
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</tbody>
</table>

calcium carbonate 1.25 g (calcium 500 mg) chewable tablet, 120

<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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<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>19.95</td>
<td>6.60</td>
<td>Cal-500 [PP]</td>
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</tbody>
</table>

**OTHER MINERAL SUPPLEMENTS**

**Magnesium**

**MAGNESIUM**

Restricted benefit

Hypomagnesaemia

The condition must be documented in the patient's medical records.
magnesium 37.4 mg tablet, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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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>
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<td>18.04</td>
<td>6.60</td>
<td></td>
<td>Amcal Mag-A [IG]</td>
<td>Mag-Sup [PP]</td>
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<tr>
<td></td>
<td>..</td>
<td>18.61</td>
<td>6.60</td>
<td></td>
<td>Pharmacy Care Magnesium</td>
<td>Magmin [BB]</td>
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</tbody>
</table>

### BLOOD AND BLOOD FORMING ORGANS

#### ANTITHROMBOTIC AGENTS

**Platelet aggregation inhibitors excl. heparin**

### ASPIRIN

#### aspirin 100 mg tablet, 112

<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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<tr>
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<td></td>
<td></td>
<td>Spren 100 [OW]</td>
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#### aspirin 100 mg tablet, 90

<table>
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</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cardiprin 100 [RC]</td>
</tr>
</tbody>
</table>

### ASPIRIN

**Note** The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.

#### aspirin 100 mg enteric capsule, 84

<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>
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<td></td>
<td></td>
<td></td>
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<td>Astrix [YN]</td>
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#### aspirin 100 mg enteric tablet, 84

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<th>DPMQ $</th>
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<td></td>
<td>Cardasa [AF]</td>
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<td></td>
<td>Cartia [AS]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Pharmacy Action Low Dose Aspirin [GQ]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Trust Aspirin EC 100 [CR]</td>
</tr>
</tbody>
</table>

### CLOPIDOGREL

**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.

**Authority required**

For use in patients pre- and post-angioplasty

#### clopidogrel 75 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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<tbody>
<tr>
<td>1</td>
<td>3</td>
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<td></td>
<td></td>
<td>BTC Clopidogrel [JB]</td>
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<td></td>
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<td>Clopidogrel APOTEX [GX]</td>
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<td></td>
<td>Clopidogrel GH [GQ]</td>
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<td>Pldigrel [RF]</td>
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<td>Blooms the Chemist</td>
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<td></td>
<td></td>
<td>Clopidogrel Sandoz Pharma [HX]</td>
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<td></td>
<td></td>
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<td>Piax [AF]</td>
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#### clopidogrel 75 mg tablet, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>APO-Clopidogrel [TX]</td>
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<td>Clopidogrel AN [EA]</td>
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<td>Iscover [AV]</td>
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<td>Plavicor 75 [CR]</td>
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<td></td>
<td>Clopidogrel Sandoz Pharma [HX]</td>
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<td></td>
<td>Piax [AF]</td>
</tr>
</tbody>
</table>

### ANTIANEMIC PREPARATIONS

#### IRON PREPARATIONS

**Iron bivalent, oral preparations**

#### FERROUS FUMARATE

ferrous fumarate 200 mg (iron 65.7 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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>18.69</td>
<td>6.60</td>
<td></td>
<td>Ferro-tab [AE]</td>
</tr>
</tbody>
</table>
### FERROUS FUMARATE + FOLIC ACID
ferrous fumarate 310 mg (iron 100 mg) + folic acid 350 microgram tablet, 60

<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>1</td>
<td>..</td>
<td>19.71</td>
<td>6.60</td>
<td>Ferro-f-tab [AE]</td>
</tr>
</tbody>
</table>

### VITAMIN B12 AND FOLIC ACID
Vitamin B12 (cyanocobalamin and analogues)

### HYDROXOCOBALAMIN
Note One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B₁₂ deficiencies.

Note Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

- **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.

hydroxocobalamin 1 mg/mL injection, 3 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>1</td>
<td>..</td>
<td>..</td>
<td>16.29</td>
<td>6.60</td>
<td>*Vita-B12 [GH]</td>
</tr>
</tbody>
</table>

hydroxocobalamin 1 mg/mL injection, 3 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>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>16.29</td>
<td>6.60</td>
<td>*Neo-B12 [PF]</td>
</tr>
</tbody>
</table>

### FOLIC ACID
defol acid 500 microgram 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>2</td>
<td>..</td>
<td>..</td>
<td>*16.08</td>
<td>6.60</td>
<td>*Foltabs 500 [PP]</td>
</tr>
</tbody>
</table>

### FOLIC ACID
Note The 5 mg strength tablet should be used in malabsorption states only.

defol acid 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>2</td>
<td>1</td>
<td>..</td>
<td>*18.30</td>
<td>6.60</td>
<td>*Megafol 0.5 [AF]</td>
</tr>
</tbody>
</table>

### BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

#### IRRIGATING SOLUTIONS
Salt solutions

#### SODIUM CHLORIDE
sodium chloride 0.9% (9 g/L) solution, 1 L bottle

<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>15.70</td>
<td>6.60</td>
<td>Baxter Healthcare Pty Ltd [BX]</td>
</tr>
</tbody>
</table>

sodium chloride 0.9% (4.5 g/500 mL) solution, 500 mL bottle

<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>15.42</td>
<td>6.60</td>
<td>Baxter Healthcare Pty Ltd [BX]</td>
</tr>
</tbody>
</table>

### CARDIOVASCULAR SYSTEM

#### VASOPROTECTIVES

**Agents for treatment of hemorrhoids and anal fissures for topical use**

*Other agents for treatment of hemorrhoids and anal fissures for topical use*
### Zinc Oxide + Peru Balsam + Benzyl Benzoate

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>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>4039N</td>
<td>Zinc oxide 10.75% + peru balsam 1.88% + benzyl benzoate 1.25% ointment, 50 g</td>
<td></td>
<td>1</td>
<td>1</td>
<td>18.99</td>
<td>6.60</td>
<td></td>
<td>Anusol [JT]</td>
</tr>
<tr>
<td>4040P</td>
<td>Zinc oxide 300 mg + peru balsam 50 mg + benzyl benzoate 33 mg suppository, 12</td>
<td></td>
<td>1</td>
<td>1</td>
<td>18.05</td>
<td>6.60</td>
<td></td>
<td>Anusol [JT]</td>
</tr>
</tbody>
</table>

### Dermatologicals

#### Antifungals for Dermatological Use

### Antifungals for Topical Use

**Imidazole and triazole derivatives**

#### Clofotrimazole

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>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>4004R</td>
<td>Clofotrimazole 1% cream, 20 g</td>
<td></td>
<td>1</td>
<td>1</td>
<td>13.78</td>
<td>6.60</td>
<td></td>
<td>* Pharmacy Action Anti-Fungal Cream [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>14.12</td>
<td>6.60</td>
<td></td>
<td>* Clonea [AF]</td>
</tr>
</tbody>
</table>

**Other antifungals for topical use**

#### Amorolfine

**Restricted benefit**

Onychomycosis

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>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>4010C</td>
<td>Amorolfine 5% solution, 5 mL</td>
<td></td>
<td>1</td>
<td></td>
<td>48.58</td>
<td>6.60</td>
<td></td>
<td>* Myconail [AE]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>68.66</td>
<td>6.60</td>
<td></td>
<td>* Pharmacy Action Anti-Fungal Nail Treatment [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>84.83</td>
<td>6.60</td>
<td></td>
<td>* Aporyl [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>93.58</td>
<td>6.60</td>
<td></td>
<td>* Loceryl [GA]</td>
</tr>
</tbody>
</table>

#### Terbinafine

**Restricted benefit**

Tinea pedis

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>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>4463X</td>
<td>Terbinafine 1% gel, 15 g</td>
<td></td>
<td>1</td>
<td></td>
<td>26.74</td>
<td>6.60</td>
<td></td>
<td>Lamisil DermGel [GK]</td>
</tr>
<tr>
<td>4473K</td>
<td>Terbinafine hydrochloride 1% cream, 15 g</td>
<td></td>
<td>1</td>
<td></td>
<td>25.47</td>
<td>6.60</td>
<td></td>
<td>* Lamisil [GK]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Pharmacy Action Pharmisil [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Trust Terbinafine Cream [CR]</td>
</tr>
</tbody>
</table>

#### Tolnaftate

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>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>4481W</td>
<td>Tolnaftate 0.07% spray, 100 g</td>
<td></td>
<td>1</td>
<td></td>
<td>19.56</td>
<td>6.60</td>
<td></td>
<td>Tinaderm [BN]</td>
</tr>
</tbody>
</table>

### Antifungals for Systemic Use

**Antifungals for systemic use**

#### Terbinafine

**Authority required**

Onychomycosis

**Clinical criteria:**

- The condition must be due to dermatophyte infection proven by microscopy and confirmed by an Approved Pathology Provider; OR
- The condition must be due to dermatophyte infection proven by culture and confirmed by an Approved Pathology Provider.
terbinafine 250 mg tablet, 42

<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>30.93</td>
<td>6.60</td>
<td>* APO-Terbinafine [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Lamisil (Novartis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pharmaceuticals Australia</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pty Limited) [NV]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Tamsil [RW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Terbinafine Sandoz [SZ]</td>
</tr>
</tbody>
</table>

**EMOLLIENTS AND PROTECTIVES**

**EMOLLIENTS AND PROTECTIVES**

**Soft paraffin and fat products**

**WOOL ALCOHOLS**

wool alcohols 6% ointment, 100 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>18.77</td>
<td>6.60</td>
<td>Eucerin [BE]</td>
</tr>
</tbody>
</table>

**UREA**

urea 10% cream, 100 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>2</td>
<td></td>
<td>17.04</td>
<td>6.60</td>
<td>Aquacare H.P. [AG]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Urederm [KY]</td>
</tr>
</tbody>
</table>

**GELATIN + PECTIN + CARMELOLOSE SODIUM**

gelatin 16.7% + pectin 16.7% + carmellose sodium 16.7% paste, 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></td>
<td>16.74</td>
<td>6.60</td>
<td>Orabase [AS]</td>
</tr>
</tbody>
</table>

**GLYCEROL + WHITE SOFT PARAFFIN**

glycerol 5% + white soft paraffin 5% lotion, 1 L

<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>31.22</td>
<td>6.60</td>
<td>QV Skin Lotion [EO]</td>
</tr>
</tbody>
</table>

**SKIN EMOLLIENT**

SKIN EMOLLIENT Bath oil 500 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>2</td>
<td></td>
<td>21.52</td>
<td>6.60</td>
<td>Alpha Keri Bath Oil [MT]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>QV Bath Oil [EO]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Hamilton Skin Therapy Oil [KY]</td>
</tr>
</tbody>
</table>

SKIN EMOLLIENT Lotion 500 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>2</td>
<td></td>
<td>21.52</td>
<td>6.60</td>
<td>Alpha Keri Lotion [MT]</td>
</tr>
</tbody>
</table>

**PROTECTIVES AGAINST UV-RADIATION**

Protectives against UV-radiation for topical use

**BEMOTRIZINOL + OCTOCRYLENE + DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE + TITANIUM DIOXIDE**

bemotrizinol 1% + octocrylene 2% + diethylamino hydroxybenzoyl hexyl benzoate 3.5% + titanium dioxide 2% lotion, 125 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>2</td>
<td></td>
<td>22.13</td>
<td>6.60</td>
<td>Sunsense Ultra SPF 50+ [EO]</td>
</tr>
</tbody>
</table>

**SUNSCREENS**

SUNSCREENS Cream 75 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>‡1</td>
<td>2</td>
<td></td>
<td>22.13</td>
<td>6.60</td>
<td>Sunsense Sensitive SPF 50+ [EO]</td>
</tr>
</tbody>
</table>
**Schedule of Pharmaceutical Benefits – December 2020**

### SUNSCREENS

<table>
<thead>
<tr>
<th>Lotion (non-alcoholic) 125 mL, 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>4546G</td>
</tr>
</tbody>
</table>

### ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

#### ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

*Anesthetics for topical use*

### LIDOCAINE (LIGNOCAINE)

<table>
<thead>
<tr>
<th>Lidocaine (lignocaine) hydrochloride 2% oral liquid, 200 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>4308R</td>
</tr>
</tbody>
</table>

#### Other antipruritics

### TAR + TROLAMINE LAURIL SULFATE

*Note* For patients who have failed to respond to simple moisturising agents.

<table>
<thead>
<tr>
<th>Tar 2.3% + trolamine lauril sulfate 6% solution, 500 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>4408B</td>
</tr>
</tbody>
</table>

### ANTIPSORIATICS

#### ANTIPSORIATICS FOR TOPICAL USE

*Tars*

### COAL TAR SOLUTION + PHENOL + PRECIPITATED SULFUR

<table>
<thead>
<tr>
<th>Coal tar solution 5% + phenol 0.5% + precipitated sulfur 0.5% gel, 30 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>4505D</td>
</tr>
</tbody>
</table>

### ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

#### ANTIBIOTICS FOR TOPICAL USE

*Other antibiotics for topical use*

### MUPIROCIN

<table>
<thead>
<tr>
<th>Mupirocin 2% ointment, 15 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>4350Y</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

#### MUPIROCIN

*Restricted benefit*

Secondarily infected traumatic skin lesions

<table>
<thead>
<tr>
<th>Mupirocin 2% cream, 15 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>4348W</td>
</tr>
</tbody>
</table>

#### CHEMOTHERAPEUTICS FOR TOPICAL USE

*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.

<table>
<thead>
<tr>
<th>Ingenol mebutate 0.015% gel, 3 x 470 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2464Q</td>
</tr>
</tbody>
</table>
DERMATOLOGICALS

- **INGENOL MEBUTATE**
  Authority required
  Solar (actinic) keratosis
  Clinical criteria:
  - Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

  **ingenol mebutate 0.05% gel, 2 x 470 mg**

<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>141.22</td>
<td>6.60</td>
<td></td>
<td>Pico [LO]</td>
</tr>
</tbody>
</table>

- **CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS**
  **CORTICOSTEROIDS, weak (group I)**

  **HYDROCORTISONE ACETATE**
  hydrocortisone acetate 1% cream, 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>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>17.19</td>
<td>6.60</td>
<td></td>
<td>&quot;Pharmacy Action Hydrocortisone Cream 1% [GQ]&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&quot;Trust HydroCortic Cream [CR]&quot;</td>
</tr>
</tbody>
</table>

  **HYDROCORTISONE ACETATE**
  Restricted benefit
  Corticosteroid-responsive dermatoses

  hydrocortisone acetate 1% ointment, 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>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>17.19</td>
<td>6.60</td>
<td></td>
<td>Cortic-DS 1% [AS]</td>
</tr>
</tbody>
</table>

  **Corticosteroids, potent (group III)**

  **BETAMETHASONE VALERATE**
  betamethasone (as valerate) 0.1% cream, 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>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>2</td>
<td>25.94</td>
<td>6.60</td>
<td></td>
<td>Betnovate [AS]</td>
</tr>
</tbody>
</table>

  betamethasone (as valerate) 0.1% ointment, 30 g

<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>2</td>
<td>25.94</td>
<td>6.60</td>
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<td>Betnovate [AS]</td>
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- **MOMETASONE**
  Note Application to large areas of skin for longer than four weeks is not recommended.

  mometasone furoate 0.1% cream, 50 g

<table>
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<tr>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>‡1</td>
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<td>Elocon [AL]</td>
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  mometasone furoate 0.1% ointment, 50 g

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<td>‡1</td>
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<td>6.60</td>
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<td>&quot;Elocon [AL]&quot;</td>
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<td>&quot;Momasone [AS]&quot;</td>
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</table>

- **ANTISEPTICS AND DISINFECTANTS**
  **ANTISEPTICS AND DISINFECTANTS**
  **Iodine products**

  **POVIDONE-IODINE**
  povidone-iodine 10% solution, 100 mL

<table>
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<tbody>
<tr>
<td>‡1</td>
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- **OTHER DERMATOLOGICAL PREPARATIONS**
  **OTHER DERMATOLOGICAL PREPARATIONS**
  **Medicated shampoos**
## DERMATOLOGICALS

- **SALICYLIC ACID + BENZALKONIUM CHLORIDE + ALCOHOL + COAL TAR SOLUTION + POLYOXYETHYLENE Ethers**

  **SALICYLIC ACID with COAL TAR SOLUTION Scalp cleanser 20 mg-50 mg per mL (2%-5%), 200 mL, 1**

<table>
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<td>24.16</td>
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- **SELENIUM SULFIDE**

  **selenium sulfide 2.5% shampoo, 125 mL**

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<td>..</td>
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<td>Selsun [DQ]</td>
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- **TAR + COAL TAR SOLUTION + SALICYLIC ACID**

  **tar 1% + coal tar solution 1% + salicylic acid 2% solution, 250 mL**

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<tbody>
<tr>
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<td>22.82</td>
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<td>Sebitar [EO]</td>
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### Wart and anti-corn preparations

- **SALICYLIC ACID + LACTIC ACID**

  **salicylic acid 16.7% + lactic acid 15% solution, 15 mL**

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### Other dermatologicals

- **DICLOFENAC**

  **Note**: Maximum quantity of four tubes (original + 3 repeats) in 12 months.

  **Authority required**

  Solar (actinic) keratosis
  Treatment Phase: Management

  **Clinical criteria:**
  - Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

  **diclofenac sodium 3% gel, 25 g**

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- **GLYCEROL**

  **glycerol 15% solution, 1 kg**

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<tr>
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- **ICHTHAMMOL**

  **Note**: For patients who have failed to respond to simple moisturising agents.

  **ichthammol 1% cream, 50 g**

<table>
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<td>Egoderm Cream [EO]</td>
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- **ICHTHAMMOL + ZINC OXIDE**

  **Note**: For patients who have failed to respond to simple moisturising agents.

  **ichthammol 1% + zinc oxide 15% ointment, 50 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
<tr>
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<td>6.60</td>
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- **IMIQUIMOD**

  **Authority required**

  Superficial basal cell carcinoma
  Treatment Phase: Primary treatment

  **Clinical criteria:**
  - The condition must be confirmed by a histological diagnosis, AND
  - The condition must be one where other standard treatments are inappropriate, AND
  - The condition must require topical drug therapy.
### IMIQUIMOD

**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.

**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.

### LIGHT LIQUID PARAFFIN + COCOAMPHODIACETATE DISODIUM

**light liquid paraffin 3.5% + cocoamphodiacetate disodium 3% lotion, 500 mL**

### PANTHENOL

**Note** To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).

### ZINC OXIDE + MAIZE STARCH + PURIFIED TALC + CHLORPHENESIN

**zinc oxide 25% + maize starch 55.85% + purified talc 18.07% + chlorphenesin 1% powder, 100 g**

### GENITO URINARY SYSTEM AND SEX HORMONES

**GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS**

**ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS**

**Antibiotics**

### NYSTATIN

**nystatin 20 000 units/g vaginal cream, 75 g**

### CLOTRIMAZOLE

**clotrimazole 2% vaginal cream, 20 g**

**clotrimazole 1% vaginal cream, 35 g**
### OTHER GYNECOLOGICALS

**ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID**

<table>
<thead>
<tr>
<th>acetic acid 0.94% + oxyquinoline sulfate 0.025% + ricinoleic acid 0.75% vaginal gel, 100 g</th>
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### UROLOGICALS

**Drugs used in erectile dysfunction**

#### ALPROSTADIL

**Authority required**

Erectile dysfunction

**Clinical criteria:**
- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**
- Patient must be male. Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

<table>
<thead>
<tr>
<th>alprostadil 10 microgram injection [1 chamber] (&amp;) inert substance diluent [0.5 mL chamber], 2 dual chamber syringes</th>
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<tbody>
<tr>
<td>4579B</td>
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<tbody>
<tr>
<td>3</td>
<td>3</td>
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<td>*106.59</td>
<td>6.60</td>
<td>Caverject Impulse [PF]</td>
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<table>
<thead>
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<th>alprostadil 20 microgram injection [1 chamber] (&amp;) inert substance diluent [0.5 mL chamber], 2 dual chamber syringes</th>
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<tr>
<td>3</td>
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<td>..</td>
<td>*134.91</td>
<td>6.60</td>
<td>Caverject Impulse [PF]</td>
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</tbody>
</table>

#### AVANAFIL

**Authority required**

Erectile dysfunction

**Clinical criteria:**
- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**
- Patient must be male. Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

<table>
<thead>
<tr>
<th>avanafil 100 mg tablet, 4</th>
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</thead>
<tbody>
<tr>
<td>11861G</td>
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<table>
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<tr>
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<td>52.88</td>
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<td>Spedra [FK]</td>
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<td>6.60</td>
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#### SILDENAFIL

**Authority required**

Erectile dysfunction

**Clinical criteria:**
- The condition must be vasculogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**
- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

### sildenafil 100 mg tablet, 4

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<tr>
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<tr>
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<td>72.54</td>
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<td>* APO-Sildenafil [TX]</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Sildenafil Actavis [EA]</td>
<td>* Sildenafil Sandoz [GX]</td>
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<td></td>
<td></td>
<td></td>
<td>* Sildenafil generichealth [GQ]</td>
<td>* Sildenafil Sandoz [SZ]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Vasafil 100 [RW]</td>
<td>* Vedafil [AF]</td>
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### sildenafil 25 mg tablet, 4

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<td>55.97</td>
<td>6.60</td>
<td></td>
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<td>* Sildenafil APOTEX [GX]</td>
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<td>* Vasafil 25 [RW]</td>
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### sildenafil 50 mg tablet, 4

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<td>* Sildenafil Sandoz [SZ]</td>
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### TADALAFIL

**Authority required**

**Erectile dysfunction**

**Clinical criteria:**
- The condition must be vascuogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**
- Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

### tadalafil 10 mg tablet, 4

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<td>* Cialis [LY]</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Cipla Tadalafil [LR]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Cipla Tadalafil [LR]</td>
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<td></td>
<td></td>
<td></td>
<td>* Tadalaccord [CR]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Tadalafil Sandoz [SZ]</td>
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### VARDENAFIL

**Authority required**

**Erectile dysfunction**

**Clinical criteria:**
- The condition must be vascuogenic; OR
- The condition must be psychogenic; OR
- The condition must be neurogenic, **AND**
- Patient must have a specific accepted war-caused or service-related disability.

**Population criteria:**
- Patient must be male.

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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**GENITO URINARY SYSTEM AND SEX HORMONES**

**vardenafil 20 mg tablet, 4**

4302K

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**Other urologicals**

- **BICARBONATE + CITRIC ACID + TARTARIC ACID**
  
  Note: Pharmaceutical benefits that have the forms sodium bicarbonate 1.76 g + sodium citrate 630 mg + citric acid 720 mg + tartaric acid 890 mg powder for oral liquid and sodium bicarbonate 1.76 g + citric acid 720 mg + sodium citrate 630 mg + tartaric acid 890 mg effervescent granules are equivalent for the purposes of substitution.

  **Restricted benefit**
  
  Urinary symptoms
  
  **Clinical criteria:**
  
  - The treatment must be for when antibiotic or other therapy alone is inappropriate.

  **sodium bicarbonate 1.76 g + sodium citrate 630 mg + citric acid 720 mg + tartaric acid 890 mg powder for oral liquid, 28 x 4 g sachets**

  4049D

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  **sodium bicarbonate 1.76 g + citric acid 720 mg + sodium citrate 630 mg + tartaric acid 890 mg effervescent granules, 28 x 4 g sachets**

  12179B

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<td>6.60</td>
<td>a Trust Cystitis Relief [CR]</td>
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**DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY**

- **Alpha-adrenoreceptor antagonists**

  **ALFUZOSIN**

  **Authority required**
  
  Benign prostatic hyperplasia
  
  **Clinical criteria:**
  
  - Patient must have lower urinary tract symptoms.

  **alfuzosin hydrochloride 10 mg modified release tablet, 30**

  4277D

<table>
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<td>63.78</td>
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<td>Xatral SR [SW]</td>
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</table>

  **DUTASTERIDE + TAMSULOSIN**

  **Authority required**
  
  Benign prostatic hyperplasia
  
  **Clinical criteria:**
  
  - Patient must have lower urinary tract symptoms.

  **dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram modified release capsule, 30**

  10102Q

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  **SILODOSIN**

  **Authority required**
  
  Benign prostatic hyperplasia
  
  **Clinical criteria:**
  
  - Patient must have lower urinary tract symptoms.

  **silodosin 4 mg capsule, 30**

  12079R

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  **silodosin 8 mg capsule, 30**

  12077P

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  **TAMSULOSIN**

  **Authority required**
  
  Benign prostatic hyperplasia
  
  **Clinical criteria:**
  
  - Patient must have lower urinary tract symptoms.
tamsulosin hydrochloride 400 microgram modified release tablet, 30

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| Testosterone-5-alpha reductase inhibitors |

**DUTASTERIDE**

*Authority required*

Benign prostatic hyperplasia

**Clinical criteria:**
- Patient must have lower urinary tract symptoms.

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<th>dutasteride 500 microgram capsule, 30</th>
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**FINASTERIDE**

*Authority required*

Benign prostatic hyperplasia

**Clinical criteria:**
- Patient must have lower urinary tract symptoms.

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<th>finasteride 5 mg tablet, 28</th>
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**ANTIINFECTIVES FOR SYSTEMIC USE**

**ANTIBACTERIALS FOR SYSTEMIC USE**

**MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS**

**Macrolides**

**AZITHROMYCIN**

*Restricted benefit*

Upper and lower respiratory tract infections

<table>
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**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

**ANTINEOPLASTIC AGENTS**

**ANTIMETABOLITES**

Pyrimidine analogues

**FLUOROURACIL**

fluorouracil 5% cream, 20 g

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**IMMUNOSUPPRESSANTS**

**IMMUNOSUPPRESSANTS**

*Tumor necrosis factor alpha (TNF-α) inhibitors*
INFLIXIMAB

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

Authority required

Initial treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Initial treatment may be prescribed by rheumatologists or consultant physicians for the reduction of signs and symptoms and prevention of structural joint damage in adult patients with active rheumatoid arthritis who satisfy all of the following criteria:

1. (a) Proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP); and
2. (b) Proven erosive rheumatoid arthritis without end-stage disease;
3. Failure of an adequate trial of methotrexate and 2 other disease modifying anti-rheumatic drugs (such as sulfasalazine, hydroxychloroquine, leflunomide or cyclosporin) — unless these drugs were contraindicated or intolerance had developed;
4. No history of active tuberculosis requiring treatment in the last 3 years;
5. No history of opportunistic infection in the last 2 months;
6. Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

Authority required

Continuing treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Continuing treatment may be prescribed by rheumatologists or consultant physicians, following initial therapy of 3 doses, in patients who satisfy the following criteria:

1. There is improvement in ESR and/or CRP; and
2. An ACR20 (American College of Rheumatology) response is achieved by 14 weeks after the commencement of therapy.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

infliximab 100 mg injection, 1 vial

<table>
<thead>
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MUSCULO-SKELETAL SYSTEM

TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

Preparations with salicylic acid derivatives

METHYL SALICYLATE + MENTHOL + CAMPHOR + EUCALYPTUS OIL + PINE OIL PUMILIO + TURPENTINE OIL + PEPPERMINT OIL + CAJUPUT OIL + CAPSICUM EXTRACT

methyl salicylate 20% + menthol 5% + camphor 3.5% + eucalyptus oil 3% + pine oil pumilio 1% + turpentine oil 1% + peppermint oil 0.5% + cajuput oil 0.5% + capsicum extract 0.15% cream, 100 g

<table>
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DRUGS FOR TREATMENT OF BONE DISEASES

Bisphosphonates

RISEDRONATE

Authority required

Preservation of bone mineral density

Clinical criteria:

- Patient must be on long-term glucocorticoid therapy, AND
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, AND
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).
Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

### ALENDRONATE + COLECALCIFEROL

**Authority required**
Preservation of bone mineral density

**Clinical criteria:**
- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

### RISEDRONATE (&) CALCIUM CARBONATE

**Authority required**
Preservation of bone mineral density

**Clinical criteria:**
- Patient must be on long-term glucocorticoid therapy, **AND**
- Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, **AND**
- Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

---

### NERVOUS SYSTEM

#### ANALGESICS

#### OPIOIDS

**Natural opium alkaloids**

#### MORPHINE

**Caution** The risk of drug dependence is high.

**Note** Authorities for increased maximum quantities and/or repeats will be granted only for:
- (i) chronic severe disabling pain associated with proven malignant neoplasia; or
- (ii) chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.

**Restricted benefit**

---

Repatriation Pharmaceutical Benefits Scheme
Chronic severe disabling pain

**Clinical criteria:**
- The condition must be unresponsive to non-opioid analgesics.

**morphine sulfate pentahydrate 200 mg modified release tablet, 28**

<table>
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**Opioids in combination with non-opioid analgesics**

**ASPIRIN + CODEINE**

**aspirin 300 mg + codeine phosphate hemihydrate 8 mg dispersible tablet, 40**

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**PARACETAMOL + CODEINE**

**paracetamol 500 mg + codeine phosphate hemihydrate 8 mg tablet, 40**

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**OTHER ANALGESICS AND ANTIPYRETICS**

**Anilides**

**PARACETAMOL**

**paracetamol 240 mg/5 mL oral liquid, 200 mL**

<table>
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<tr>
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<td>* Panamax 240 Elixir [SW]</td>
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**paracetamol 500 mg tablet, 100**

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<tr>
<td></td>
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<td></td>
<td>* Trust for Kids Paracetamol 6 to 12 years [CR]</td>
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</table>

**PARACETAMOL**

**Restricted benefit**

Persistent pain

**Clinical criteria:**
- The condition must be associated with osteoarthritis.

**paracetamol 665 mg modified release tablet, 96**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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**PARACETAMOL**

**Restricted benefit**

Chronic arthropathies

**paracetamol 500 mg tablet, 100**

<table>
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<td>*16.98</td>
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**Other analgesics and antipyretics**

**GABAPENTIN**

**Authority required**

Refractory neuropathic pain

**Clinical criteria:**
- The condition must be unable to be controlled by other drugs.

**gabapentin 800 mg tablet, 100**

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<td>50.99</td>
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NERVOUS SYSTEM

PSYCHOLEPTICS

ANXIOLYTICS

BENZODIAZEPINE derivatives

BROMAZEPAM

Note This drug should not be used as the first line of treatment.
Note Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.
Note 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.

Authority required
Terminal disease
Clinical criteria:
• The treatment must be for the short-term, AND
• Patient must be receiving palliative care.

Authority required
Refractory phobic or anxiety states
Clinical criteria:
• The treatment must be for the short-term.

bromazepam 3 mg tablet, 30

4150K Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
2 .. .. 32.08 6.60 Lexotan [PB]

bromazepam 6 mg tablet, 30

4151L Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
2 .. .. 37.82 6.60 Lexotan [PB]

Azaspirodecanedione derivatives

BUSPIRONE

Authority required
Anxiety
Clinical criteria:
• The treatment must be for the short-term.

buspirone hydrochloride 5 mg tablet, 50

4144D Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 .. .. 39.47 6.60 Buspar [AS]

Gabapentin APOTEX [TY]
Gabapentin APOTEX [CR]
Gabapentin Aspen 800 [RW]
Neurontin [UJ]

Gabapentin APOTEX [TY]
Gabapentin APOTEX [CR]
Gabapentin Aspen 800 [RW]
Neurontin [UJ]

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Gabapentin Aspen 800 [RW]
Neurontin [UJ]

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Gabapentin APOTEX [CR]
Gabapentin Aspen 800 [RW]
Neurontin [UJ]
### HYPNOTICS AND SEDATIVES

**Benzodiazepine derivatives**

- **FLUNITRAZEPAM**
  
  **Note** This drug should not be used as the first line of treatment.
  
  **Note** 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.

  **Authority required**
  
  **Terminal disease**
  
  **Clinical criteria:**
  - The treatment must be for the short-term, AND
  - Patient must be receiving palliative care.

  **Authority required**
  
  **Refractory phobic or anxiety states**
  
  **Clinical criteria:**
  - The treatment must be for the short-term.

- **ZOPICLONE**
  
  **Restricted benefit**
  
  **Insomnia**
  
  **Clinical criteria:**
  - The treatment must be for the short-term.

- **OTHER NERVOUS SYSTEM DRUGS**

- **DRUGS USED IN ADDICTIVE DISORDERS**

- **NICOTINE**
  
  **Note** Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.

  **Authority required**
  
  **Nicotine dependence**
  
  **Clinical criteria:**
  - Patient must have indicated they are ready to cease smoking, AND
  - Patient must have entered a comprehensive support and counselling program.

### BUSPIRONE HYDROCHLORIDE 10 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>4145E</td>
<td></td>
<td></td>
<td>55.94</td>
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<td>Buspar [AS]</td>
</tr>
</tbody>
</table>

### FLUNITRAZEPAM 1 mg tablet, 30

<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>4216X</td>
<td></td>
<td>21.82</td>
<td>6.60</td>
<td></td>
<td>Hypnodorm [AF]</td>
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</table>

### ZOPICLONE 7.5 mg tablet, 30

<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>4522B</td>
<td></td>
<td>25.36</td>
<td>6.60</td>
<td></td>
<td>* APO-Zopiclone [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Imrest [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Zopiclone GH [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Pharmacor Zopiclone [CR]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Imovane [SW]</td>
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</tbody>
</table>

### NICOTINE 14 mg/24 hours patch, 7

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>4572P</td>
<td></td>
<td>*55.66</td>
<td>6.60</td>
<td></td>
<td>QuitX [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>*58.68</td>
<td>6.60</td>
<td></td>
<td>Nicabate CQ 14 [GC]</td>
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</tbody>
</table>

### NICOTINE 21 mg/24 hours patch, 7

<table>
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<tr>
<td>4573Q</td>
<td></td>
<td>*58.62</td>
<td>6.60</td>
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<td>QuitX [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>*68.68</td>
<td>6.60</td>
<td></td>
<td>Nicabate CQ 21 [GC]</td>
</tr>
</tbody>
</table>

### NICOTINE 7 mg/24 hours patch, 7

<table>
<thead>
<tr>
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4571N</td>
<td></td>
<td>*52.50</td>
<td>6.60</td>
<td></td>
<td>QuitX [AF]</td>
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</table>
**ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS**

**ANTHELMINTICS**

**ANTHELMINTIC AGENTS**

*Benzimidazole derivatives*

**MEBENDAZOLE**

*Note* Pharmaceutical benefits that have the forms mebendazole 100 mg tablet and mebendazole 100 mg chewable tablet are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
<th>Antiparasitic Products, Insecticides and Repellents</th>
<th>INSECTICIDES AND REPELLENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS</strong></td>
<td><strong>ANTHELMINTIC AGENTS</strong></td>
</tr>
<tr>
<td><strong>ANTHELMINTIC AGENTS</strong></td>
<td><strong>Benzimidazole derivatives</strong></td>
</tr>
<tr>
<td><strong>MEBENDAZOLE</strong></td>
<td><strong>MEBENDAZOLE</strong></td>
</tr>
</tbody>
</table>

### mebendazole 100 mg tablet, 6

<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>4325P</td>
<td>1</td>
<td>..</td>
<td>18.22</td>
<td>6.60</td>
<td>* Pharmacy Action Worm Treatment [GQ]</td>
</tr>
</tbody>
</table>

### mebendazole 100 mg chewable tablet, 6

<table>
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<th>Max Qty Packs</th>
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<tr>
<td>12194T</td>
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<td>18.22</td>
<td>6.60</td>
<td>* Trust Deworm [CR]</td>
</tr>
</tbody>
</table>

**RESPIRATORY SYSTEM**

**NASAL PREPARATIONS**

**DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE**

*Sympathomimetics, plain*

**OXYMETAZOLINE**

<table>
<thead>
<tr>
<th>Antiparasitic Products, Insecticides and Repellents</th>
<th>INSECTICIDES AND REPELLENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE</strong></td>
<td><strong>Sympathomimetics, plain</strong></td>
</tr>
<tr>
<td><strong>OXYMETAZOLINE</strong></td>
<td><strong>OXYMETAZOLINE</strong></td>
</tr>
</tbody>
</table>

### oxymetazoline hydrochloride 0.05% 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>
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</thead>
<tbody>
<tr>
<td>4378K</td>
<td>1</td>
<td>..</td>
<td>21.35</td>
<td>6.60</td>
<td>Drixine [BN]</td>
</tr>
</tbody>
</table>

### oxymetazoline hydrochloride 0.05% nasal spray, 18 mL

<table>
<thead>
<tr>
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<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4379L</td>
<td>1</td>
<td>..</td>
<td>21.01</td>
<td>6.60</td>
<td>Logicin Rapid Relief [AS]</td>
</tr>
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</table>

### oxymetazoline hydrochloride 0.05% nasal spray, 20 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>11711J</td>
<td>1</td>
<td>..</td>
<td>21.01</td>
<td>6.60</td>
<td>* Pharmacy Action Nasal Decongestant [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Trust Decongestant Nasal Spray [CR]</td>
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</table>

**Antiallergic agents, excl. corticosteroids**

**CROMOGLYCATE**

<table>
<thead>
<tr>
<th>Antiparasitic Products, Insecticides and Repellents</th>
<th>INSECTICIDES AND REPELLENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CROMOGLYCATE</strong></td>
<td><strong>CROMOGLYCATE</strong></td>
</tr>
</tbody>
</table>

### sodium cromoglycate 2% nasal spray, 26 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>
</tr>
</thead>
<tbody>
<tr>
<td>4468E</td>
<td>1</td>
<td>5</td>
<td>26.36</td>
<td>6.60</td>
<td>Rynacrom [SW]</td>
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</tbody>
</table>

**Corticosteroids**

**BUDESONIDE**

*Restricted benefit*

Severe intractable rhinitis

<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>4092J</td>
<td>1</td>
<td>..</td>
<td>42.61</td>
<td>6.60</td>
<td>Budamax Aqueous [JT]</td>
</tr>
</tbody>
</table>

**Other nasal preparations**

**IPRATROPIUM**

*Restricted benefit*

Severe intractable rhinorrhoea

**Clinical criteria:**

- The condition must be associated with perennial rhinitis, **AND**
- The condition must be unresponsive to insufflated nasal steroids.

### ipratropium bromide monohydrate 44 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>4090G</td>
<td>1</td>
<td>5</td>
<td>33.56</td>
<td>6.60</td>
<td>Atrovent Nasal Forte [VZ]</td>
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</tbody>
</table>
**SENSORY ORGANS**

**NASAL DECONGESTANTS FOR SYSTEMIC USE**

**Sympathomimetics**

- **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>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>15.37</td>
<td>6.60</td>
<td></td>
<td>* Pharmacy Action Sinus &amp; Nasal Decongestant Relief [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>16.02</td>
<td>6.60</td>
<td></td>
<td>* Logisin Sinus [AS]</td>
</tr>
</tbody>
</table>

**ANTIHISTAMINES FOR SYSTEMIC USE**

**Piperazine derivatives**

- **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>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>28.99</td>
<td>6.60</td>
<td></td>
<td>* Pharmacy Action Getrelief [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>32.22</td>
<td>6.60</td>
<td></td>
<td>* Alzene [AF]</td>
</tr>
</tbody>
</table>

**Other antihistamines for systemic use**

- **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>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1</td>
<td>..</td>
<td>28.81</td>
<td>6.60</td>
<td></td>
<td>* Pharmacy Action Fexorelief 120 [GQ]</td>
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<tr>
<td></td>
<td></td>
<td>32.02</td>
<td>6.60</td>
<td></td>
<td>* Xergic [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>48.23</td>
<td>6.60</td>
<td></td>
<td>* Telfast 120 [SW]</td>
</tr>
</tbody>
</table>

- **fexofenadine hydrochloride 60 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>3</td>
<td>..</td>
<td>*56.10</td>
<td>6.60</td>
<td></td>
<td>Telfast [SW]</td>
</tr>
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</table>

- **loratadine 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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<tr>
<td>1</td>
<td>..</td>
<td>31.42</td>
<td>6.60</td>
<td></td>
<td>* Pharmacy Action Lorastyne [GQ]</td>
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<tr>
<td></td>
<td></td>
<td>35.12</td>
<td>6.60</td>
<td></td>
<td>* Trust Loratadine [CR]</td>
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<td></td>
<td></td>
<td>44.75</td>
<td>6.60</td>
<td></td>
<td>* Allerze [AF]</td>
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<td></td>
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<td>47.02</td>
<td>6.60</td>
<td></td>
<td>* Claratyne [BN]</td>
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</tbody>
</table>

**SENSORY ORGANS**

**OTOLOGICALS**

**OTHER OTOLOGICALS**

**Indifferent preparations**

- **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>21.50</td>
<td>6.60</td>
<td></td>
<td>Ear Clear for Ear Wax Removal [KY]</td>
</tr>
</tbody>
</table>
### DOCUSATE

**docusate sodium 0.5% 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>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>19.02</td>
<td>6.60</td>
<td></td>
<td>Waxsol [GO]</td>
</tr>
</tbody>
</table>

### ORTHO-DICHLOROBENZENE + PARA-DICHLOROBENZENE + CHLOROBUTANOL + ARACHIS OIL

**ortho-dichlorobenzene 14% + para-dichlorobenzene 2% + chlorobutanol hemihydrate 5% + arachis oil 57% 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>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td></td>
<td>18.68</td>
<td>6.60</td>
<td></td>
<td>Cerumol [UN]</td>
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</tbody>
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### VARIOUS

### ALL OTHER THERAPEUTIC PRODUCTS

#### Drugs for treatment of hyperkalemia and hyperphosphatemia

### SODIUM POLYSTYRENE SULFONATE

**sodium polystyrene sulfonate 999.3 mg/g powder, 454 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>
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<td>1</td>
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<td>70.84</td>
<td>6.60</td>
<td></td>
<td>Resonium-A [SW]</td>
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</table>

### GENERAL NUTRIENTS

#### OTHER NUTRIENTS

**Other combinations of nutrients**

### PROTEIN FORMULA WITH ARGinine, VITAMIN C AND E

**Restricted benefit**

- Stage 2 and above pressure injury

**Clinical criteria:**
- The treatment must be for special medical purposes to support healing of pressure injuries.

**protein formula with arginine, vitamin C and E powder for oral liquid, 14 x 9.2 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>4</td>
<td>5</td>
<td>*161.90</td>
<td>6.60</td>
<td></td>
<td>Arginaid [NT]</td>
</tr>
</tbody>
</table>

### PROTEIN FORMULA WITH ARGinine, VITAMIN C, E AND ZINc

**Restricted benefit**

- Stage 2 and above pressure injury

**Clinical criteria:**
- The treatment must be for special medical purposes to support healing of pressure injuries.

**protein formula with arginine, vitamin C, E and zinc oral liquid, 24 x 200 mL bottles**

<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>5</td>
<td>*205.90</td>
<td>6.60</td>
<td></td>
<td>Cubitan [SB]</td>
</tr>
</tbody>
</table>

**protein formula with arginine, vitamin C, E and zinc oral liquid, 27 x 237 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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<tr>
<td>2</td>
<td>5</td>
<td>*269.16</td>
<td>6.60</td>
<td></td>
<td>Arginaid Extra [NT]</td>
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</table>

### ALL OTHER NON-THERAPEUTIC PRODUCTS

### LUBRICATING AGENT

**lubricating agent gel, 100 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></td>
<td>15.25</td>
<td>6.60</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>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>24.11</td>
<td>6.60</td>
<td></td>
<td>Surepress 650948 [CC]</td>
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**BANDAGE CALICO**

Bandage calico large triangular bandage, 1

<table>
<thead>
<tr>
<th>Max Qty</th>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>18.03</td>
<td>6.60</td>
<td></td>
<td>Handy 36361414 [BV]</td>
</tr>
</tbody>
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**BANDAGE COMPRESSION**

Bandage compression 10 cm x 3.5 m soft bandage [1] (&) bandage compression 10 cm x 6 m short stretch bandage [1], 1 pack

<table>
<thead>
<tr>
<th>Max Qty</th>
<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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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>38.61</td>
<td>6.60</td>
<td></td>
<td>Rosidal TCS 26484 [LC]</td>
</tr>
</tbody>
</table>

**BANDAGE COMPRESSION**

Note: Treatment of varices and edema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Bandage compression 10 cm x 3 m high stretch 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>5</td>
<td>..</td>
<td>..</td>
<td>*72.49</td>
<td>6.60</td>
<td></td>
<td>Surepress 650947 [CC]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>*152.69</td>
<td>6.60</td>
<td></td>
<td>Tensopress 71723-00 [BV]</td>
</tr>
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</table>

Bandage compression 8 cm x 2.6 m short stretch bandage, 1

<table>
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<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>*77.84</td>
<td>6.60</td>
<td></td>
<td>Comprilan 01027-00 [BV]</td>
</tr>
</tbody>
</table>

**BANDAGE COMPRESSION**

Note: Treatment of varices and edema associated with venous disease and lymphoedema; contraindicated in arterial disease.

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.

Bandage compression four layer 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>5</td>
<td>..</td>
<td>..</td>
<td>*186.09</td>
<td>6.60</td>
<td></td>
<td>Profore Lite 66050415 [SN]</td>
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</table>

Bandage compression four layer bandage, 1

<table>
<thead>
<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>
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</thead>
<tbody>
<tr>
<td>5</td>
<td>..</td>
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<td>*278.14</td>
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<td>Profore 66050016 [SN]</td>
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</table>

**BANDAGE COMPRESSION**

Note: Treatment of varices and edema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Molnlycke products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

Bandage compression 10 cm x 3.5 m high stretch 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>
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</thead>
<tbody>
<tr>
<td>5</td>
<td>..</td>
<td>..</td>
<td>*77.64</td>
<td>6.60</td>
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<td>Setopress 3505 [MH]</td>
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**BANDAGE COMPRESSION**

Note: Treatment of varices and edema 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 Type</th>
<th>Item Code</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>
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</thead>
<tbody>
<tr>
<td>Bandage compression two layer bandage, 1</td>
<td>4050E</td>
<td></td>
<td></td>
<td>43.78</td>
<td>6.60</td>
<td></td>
<td>Coban 2 [MM]</td>
</tr>
<tr>
<td><strong>Bandage Retention Cohesive Heavy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bandage retention cohesive heavy 10 cm x 1.3 m</td>
<td>4813H</td>
<td>2</td>
<td></td>
<td>24.76</td>
<td>6.60</td>
<td></td>
<td>Peg 7423 [MM]</td>
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<tr>
<td>Bandage retention cohesive heavy 10 cm x 2 m</td>
<td>4660G</td>
<td>2</td>
<td></td>
<td>23.28</td>
<td>6.60</td>
<td></td>
<td>Coban 1584 [MM]</td>
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<tr>
<td>Bandage retention cohesive heavy 15 cm x 1.3 m</td>
<td>4814J</td>
<td>2</td>
<td></td>
<td>30.94</td>
<td>6.60</td>
<td></td>
<td>Peg 7425 [MM]</td>
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<tr>
<td>Bandage retention cohesive heavy 5 cm x 1.3 m</td>
<td>4811F</td>
<td>2</td>
<td></td>
<td>18.62</td>
<td>6.60</td>
<td></td>
<td>Peg 7420 [MM]</td>
</tr>
<tr>
<td>Bandage retention cohesive 7.5 cm x 1.3 m</td>
<td>4812G</td>
<td>2</td>
<td></td>
<td>21.48</td>
<td>6.60</td>
<td></td>
<td></td>
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<tr>
<td><strong>Bandage Retention Cohesive Light</strong></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bandage retention cohesive light 10 cm x 2 m</td>
<td>4662J</td>
<td>2</td>
<td></td>
<td>34.40</td>
<td>6.60</td>
<td></td>
<td>Handygauze Cohesive 8635</td>
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<td>[BV]</td>
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<tr>
<td>Bandage retention cohesive light 6 cm x 2 m</td>
<td>4719J</td>
<td>2</td>
<td></td>
<td>20.54</td>
<td>6.60</td>
<td></td>
<td>Handygauze Cohesive 8633</td>
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<td>[BV]</td>
</tr>
<tr>
<td>Bandage retention cohesive light 2.5 cm x 2 m</td>
<td>4718H</td>
<td>‡1</td>
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<td>Handygauze Cohesive 8631</td>
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<td>[BV]</td>
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<tr>
<td><strong>Bandage Retention Cotton Crepe</strong></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bandage retention cotton crepe 10 cm x 2.3 m</td>
<td>4729H</td>
<td>2</td>
<td></td>
<td>28.50</td>
<td>6.60</td>
<td></td>
<td>Telfa 8254F [KE]</td>
</tr>
<tr>
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<td></td>
<td>Tensocrepe 36301001 [BV]</td>
</tr>
<tr>
<td>Bandage retention cotton crepe 5 cm x 2.3 m</td>
<td>4727T</td>
<td>2</td>
<td></td>
<td>21.58</td>
<td>6.60</td>
<td></td>
<td>Telfa 8252F [KE]</td>
</tr>
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<td>Tensocrepe 36300501 [BV]</td>
</tr>
<tr>
<td>Bandage retention cotton crepe 7.5 cm x 2.3 m</td>
<td>4728W</td>
<td>2</td>
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<td>25.76</td>
<td>6.60</td>
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<td>Telfa 8253F [KE]</td>
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<td>Tensocrepe 36307501 [BV]</td>
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<tr>
<td><strong>Bandage Tubular</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Bandage tubular size C (15 cm to 25 cm) straight</td>
<td>4663K</td>
<td>‡1</td>
<td></td>
<td>19.82</td>
<td>6.60</td>
<td></td>
<td>Elastoplast 2225 [BE]</td>
</tr>
<tr>
<td>Bandage tubular size D (25 cm to 43 cm) straight</td>
<td>4664L</td>
<td>‡1</td>
<td></td>
<td>19.82</td>
<td>6.60</td>
<td></td>
<td>Elastoplast 2226 [BE]</td>
</tr>
</tbody>
</table>
### BANDAGE TUBULAR

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<table>
<thead>
<tr>
<th>Bandage</th>
<th>Size</th>
<th>Material</th>
<th>¢1</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>Bandage tubular size E (35 cm to 45 cm) straight bandage, 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>Elastoplast 2227 [BE]</td>
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<table>
<thead>
<tr>
<th>Bandage</th>
<th>Size</th>
<th>Material</th>
<th>¢1</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>Bandage tubular 10 cm x 1 m bandage, 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tubigrip F 1548 [MH]</td>
</tr>
<tr>
<td><strong>Bandage tubular 6.25 cm x 1 m bandage, 1</strong></td>
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<td></td>
<td></td>
<td>Tubigrip B 1520 [MH]</td>
</tr>
<tr>
<td><strong>Bandage tubular 6.75 cm x 1 m bandage, 1</strong></td>
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<td>Tubigrip C 1545 [MH]</td>
</tr>
<tr>
<td><strong>Bandage tubular 7.5 cm x 1 m bandage, 1</strong></td>
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<td></td>
<td></td>
<td>Tubigrip D 1546 [MH]</td>
</tr>
<tr>
<td><strong>Bandage tubular 8.75 cm x 1 m bandage, 1</strong></td>
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<td></td>
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<td></td>
<td>Tubigrip E 1547 [MH]</td>
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</table>

### BANDAGE TUBULAR FINGER

**BANDAGE-TUBULAR (FINGER) Complete pack including applicator, 1**

<table>
<thead>
<tr>
<th>Bandage</th>
<th>Size</th>
<th>Material</th>
<th>¢1</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>Bandage tubular light weight 10 m large limb size bandage, 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tubegauz 0501633 [SS]</td>
</tr>
<tr>
<td><strong>Bandage tubular light weight 10 m medium limb size bandage, 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tubifast 2436 [MH]</td>
</tr>
<tr>
<td><strong>Bandage tubular light weight 10 m small limb size bandage, 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tubifast 2434 [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.

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<table>
<thead>
<tr>
<th>Bandage</th>
<th>Size</th>
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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><strong>Bandage tubular light weight 10 m large limb size bandage, 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tubifast 2438 [MH]</td>
</tr>
<tr>
<td><strong>Bandage tubular light weight 10 m medium limb size bandage, 1</strong></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>Tubifast 2436 [MH]</td>
</tr>
<tr>
<td><strong>Bandage tubular light weight 10 m small limb size bandage, 1</strong></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Tubifast 2434 [MH]</td>
</tr>
</tbody>
</table>

### BANDAGE TUBULAR LONG Stocking

**Note** Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com.

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<table>
<thead>
<tr>
<th>Bandage</th>
<th>Size</th>
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<th>¢1</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>Bandage tubular long stocking large size bandage, 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tubigrip 1484 [MH]</td>
</tr>
<tr>
<td><strong>Bandage tubular long stocking medium size bandage, 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tubigrip 1483 [MH]</td>
</tr>
</tbody>
</table>
### BANDAGE TUBULAR SHORT STOCKING

Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

<table>
<thead>
<tr>
<th>BANDAGE TUBULAR SHORT STOCKING</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>bandage tubular short stocking large D/E size bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*38.50</td>
<td>6.60</td>
<td>Tubigrip 1481 [MH]</td>
</tr>
<tr>
<td>bandage tubular short stocking medium C/D size bandage, 1</td>
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<td>..</td>
<td>..</td>
<td>*38.50</td>
<td>6.60</td>
<td>Tubigrip 1480 [MH]</td>
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<tr>
<td>bandage tubular short stocking small B/C size bandage, 1</td>
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<td>..</td>
<td>..</td>
<td>*38.50</td>
<td>6.60</td>
<td>Tubigrip 1479 [MH]</td>
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</table>

### BANDAGE ZINC PASTE

Note Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

<table>
<thead>
<tr>
<th>BANDAGE ZINC PASTE</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 zinc paste 10 cm x 9.1 m bandage, 1</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*31.46</td>
<td>6.60</td>
<td>Flexidress 650941 [CC]</td>
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<tr>
<td>bandage zinc paste 7.5 cm x 6 m bandage, 1</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*32.22</td>
<td>6.60</td>
<td>Steripaste 3610 [MH]</td>
</tr>
</tbody>
</table>

### BANDAGE ZINC PASTE

Note Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

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.

<table>
<thead>
<tr>
<th>BANDAGE ZINC PASTE</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 zinc paste 7.5 cm x 6 m bandage, 1</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*92.42</td>
<td>6.60</td>
<td>Viscopaste 4948 [SN]</td>
</tr>
<tr>
<td>bandage zinc paste 80 cm (stockings) bandage, 4</td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>105.90</td>
<td>6.60</td>
<td>ZipZoc 66000747 [SN]</td>
</tr>
</tbody>
</table>

### BETAIN + POLYAMINOPROPYL BIGUANIDE

betaine 0.1% + polyaminopropyl biguanide 0.1% solution, 6 x 40 mL ampoules

<table>
<thead>
<tr>
<th>BETAIN + POLYAMINOPROPYL BIGUANIDE</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>betaine 0.1% + polyaminopropyl biguanide 0.1% solution, 6 x 40 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>29.63</td>
<td>6.60</td>
<td>Prontosan Wound Irrigation Solution [BR]</td>
</tr>
</tbody>
</table>

### CADEXOMER-IODINE

Note Suitable for yellow sloughy infected and malodorous wounds.
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.

cadexomer-iodine 8 cm x 6 cm dressing, 3 x 10 g sheet

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iodosorb 66051340 [SN]</td>
<td>180.90</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

cadexomer-iodine 3 g powder, 7 sachets

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iodosorb Powder 66051070 [SN]</td>
<td>83.12</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

cadexomer-iodine 10 cm x 8 cm dressing, 2 x 17 g sheet

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iodosorb 66051360 [SN]</td>
<td>190.68</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

cadexomer-iodine 6 cm x 4 cm dressing, 5 x 5 g sheet

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iodosorb 66051230 [SN]</td>
<td>130.92</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

cadexomer-iodine 50% ointment, 4 x 10 g

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iodosorb 66051240 [SN]</td>
<td>132.18</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

cadexomer-iodine 50% ointment, 2 x 20 g

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iodosorb 66051330 [SN]</td>
<td>124.85</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

DRESSING ACTIVATED CHARCOAL MALODOROUS WOUND

dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actisorb Plus MAP105 [KI]</td>
<td>97.94</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

dressing activated charcoal malodorous wound 10 cm x 10 cm dressing, 10

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>CarboFLEX 403204 [CC]</td>
<td>77.98</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

dressing activated charcoal malodorous wound 15 cm x 20 cm dressing, 5

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>CarboFLEX 403204 [CC]</td>
<td>87.88</td>
<td>6.60</td>
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</tbody>
</table>

DRESSING ALGINATE CAVITY WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

dressing alginate cavity wound 2 g rope, 1

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorbsan 1411 [UM]</td>
<td>105.44</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

dressing alginate cavity wound 2 g rope, 5 x 2 g

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaltostat 168117 [CC]</td>
<td>110.96</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

DRESSING ALGINATE CAVITY WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfeel SeaSorb Filler 3740 [CT]</td>
<td>132.34</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>
### DRESSING ALGINATE SUPERFICIAL WOUND

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

<table>
<thead>
<tr>
<th>Dressing Alginate Superficial Wound 7.5 cm x 12 cm dressing, 10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>4683L</td>
</tr>
</tbody>
</table>

### DRESSING ALGINATE SUPERFICIAL WOUND

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**Note** 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>Dressing Alginate Superficial Wound 5 cm x 5 cm dressing, 10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>4699H</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dressing Alginate Superficial Wound 10 cm x 10 cm dressing, 10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>4700J</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dressing Alginate Superficial Wound 15 cm x 20 cm dressing, 10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>4691X</td>
</tr>
</tbody>
</table>

### DRESSING ALGINATE SUPERFICIAL WOUND

**Note** This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

<table>
<thead>
<tr>
<th>Dressing Alginate Superficial Wound 5 cm x 5 cm dressing, 1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>4684M</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dressing Alginate Superficial Wound 10 cm x 10 cm dressing, 1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>4831G</td>
</tr>
</tbody>
</table>

### DRESSING ALGINATE WITH MANUKA HONEY

**Note** Suitable for yellow sloughy infected and malodorous wounds.

<table>
<thead>
<tr>
<th>Dressing Alginate with Manuka Honey 10 cm x 10 cm dressing, 5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>10849B</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dressing Alginate with Manuka Honey 2.5 cm x 20 cm ribbon, 5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>10857K</td>
</tr>
</tbody>
</table>

### DRESSING FILM

<table>
<thead>
<tr>
<th>Dressing Film 15 cm x 20 cm dressing, 1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>4688R</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dressing Film 10 cm x 12 cm dressing, 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>4687Q</td>
</tr>
</tbody>
</table>
**VARIOUS**

*dressing film 6 cm x 7 cm dressing, 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>
</tr>
</thead>
<tbody>
<tr>
<td>$1</td>
<td>..</td>
<td>20.04</td>
<td>6.60</td>
<td></td>
<td>Nexcare Tegaderm Transparent H1624 [MM]</td>
</tr>
</tbody>
</table>

**DRESSING FILM**

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 film 10 cm x 12 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>41.35</td>
<td>6.60</td>
<td></td>
<td>Op-Site Flexigrid 4629 [SN]</td>
</tr>
</tbody>
</table>

**DRESSING FILM ISLAND**

*dressing film island 5 cm x 7 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>20.54</td>
<td>6.60</td>
<td></td>
<td>Tegaderm Transparent Island 3582 [MM]</td>
</tr>
</tbody>
</table>

*dressing film island 9 cm x 10 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>30.54</td>
<td>6.60</td>
<td></td>
<td>Tegaderm Transparent Island 3586 [MM]</td>
</tr>
</tbody>
</table>

**DRESSING FILM ISLAND**

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*dressing film island 5 cm x 7.2 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>2</td>
<td>..</td>
<td>33.80</td>
<td>6.60</td>
<td></td>
<td>Cufilm Plus 36361370 [SN]</td>
</tr>
</tbody>
</table>

*dressing film island 8 cm x 10 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>2</td>
<td>..</td>
<td>50.52</td>
<td>6.60</td>
<td></td>
<td>Cufilm Plus 36361371 [SN]</td>
</tr>
</tbody>
</table>

**DRESSING FOAM HEAVY EXUDATE**

Note This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma 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 foam heavy exudate 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>1</td>
<td>154.34</td>
<td>6.60</td>
<td></td>
<td>Allevyn 66007637 [SN]</td>
</tr>
</tbody>
</table>

**DRESSING FOAM MODERATE EXUDATE**

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 foam moderate exudate cavity conforming foam, 20 g sachet*

<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>99.85</td>
<td>6.60</td>
<td></td>
<td>Cavicare 4563 [SN]</td>
</tr>
</tbody>
</table>

**DRESSING FOAM MODERATE EXUDATE**

Note This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

Note 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 FOAM WITH SILICONE

**Note** Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

<table>
<thead>
<tr>
<th>Dressing Foam</th>
<th>Size</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>
</tr>
</thead>
<tbody>
<tr>
<td>Allevyn Adhesive</td>
<td>12.5 cm x 12.5 cm dressing, 10</td>
<td>4590N</td>
<td>1</td>
<td>153.22</td>
<td>6.60</td>
<td>6.60</td>
<td>Allevyn Adhesive 66000044 [SN]</td>
</tr>
<tr>
<td>Allevyn Life</td>
<td>10.3 cm x 10.3 cm dressing, 10</td>
<td>10017F</td>
<td>1</td>
<td>64.90</td>
<td>6.60</td>
<td>6.60</td>
<td>Allevyn Life 66801067 [SN]</td>
</tr>
<tr>
<td>Allevyn Life</td>
<td>12.9 cm x 12.9 cm dressing, 10</td>
<td>10029W</td>
<td>1</td>
<td>91.36</td>
<td>6.60</td>
<td>6.60</td>
<td>Allevyn Life 66801068 [SN]</td>
</tr>
<tr>
<td>Allevyn Life</td>
<td>15.4 cm x 15.4 cm dressing, 10</td>
<td>10023M</td>
<td>1</td>
<td>125.74</td>
<td>6.60</td>
<td>6.60</td>
<td>Allevyn Life 66801069 [SN]</td>
</tr>
<tr>
<td>Allevyn Life</td>
<td>21 cm x 21 cm dressing, 10</td>
<td>10021K</td>
<td>1</td>
<td>253.55</td>
<td>6.60</td>
<td>6.60</td>
<td>Allevyn Life 66801070 [SN]</td>
</tr>
<tr>
<td>Allevyn Life Non-Bordered</td>
<td>10.5 cm x 10.5 cm dressing, 10</td>
<td>11384E</td>
<td>1</td>
<td>64.90</td>
<td>6.60</td>
<td>6.60</td>
<td>Allevyn Life Non-Bordered 66801748 [SN]</td>
</tr>
<tr>
<td>Allevyn Life Non-Bordered</td>
<td>16 cm x 16 cm dressing, 10</td>
<td>11393P</td>
<td>1</td>
<td>110.77</td>
<td>6.60</td>
<td>6.60</td>
<td>Allevyn Life Non-Bordered 66801749 [SN]</td>
</tr>
</tbody>
</table>

### DRESSING FOAM WITH SILICONE AND SILVER

**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.

<table>
<thead>
<tr>
<th>Dressing Foam</th>
<th>Size</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>
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<tbody>
<tr>
<td>Mepilex Ag</td>
<td>10 cm x 10 cm dressing, 5</td>
<td>2439J</td>
<td>1</td>
<td>105.55</td>
<td>6.60</td>
<td>6.60</td>
<td>Mepilex Ag [MH]</td>
</tr>
<tr>
<td>Mepilex Border Ag</td>
<td>10 cm x 10 cm dressing, 5</td>
<td>2470B</td>
<td>1</td>
<td>112.63</td>
<td>6.60</td>
<td>6.60</td>
<td>Mepilex Border Ag [MH]</td>
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### DRESSING FOAM WITH SILICONE HEAVY EXUDATE

<table>
<thead>
<tr>
<th>Dressing Foam</th>
<th>Size</th>
<th>Max Qty</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>Mepilex Border Flex</td>
<td>10 cm x 10 cm dressing, 10</td>
<td>12206K</td>
<td>1</td>
<td>71.05</td>
<td>6.60</td>
<td>6.60</td>
<td>Mepilex Border Flex 595311 [MH]</td>
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<tr>
<td>Mepilex Border Flex</td>
<td>7.5 cm x 7.5 cm dressing, 10</td>
<td>12184G</td>
<td>1</td>
<td>52.99</td>
<td>6.60</td>
<td>6.60</td>
<td>Mepilex Border Flex 595211 [MH]</td>
</tr>
</tbody>
</table>
### Dressing Foam with Silicone Heavy Exudate

#### 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</th>
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</tr>
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<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td>177.95</td>
<td>6.60</td>
<td></td>
<td>Mepilex Border Flex 595611 [MH]</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td>167.55</td>
<td>6.60</td>
<td></td>
<td>Mepilex Border Heel 282750 [MH]</td>
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<tr>
<td>1</td>
<td></td>
<td></td>
<td>84.11</td>
<td>6.60</td>
<td></td>
<td>Mepilex Border Sacrum 282050 [MH]</td>
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<tr>
<td>1</td>
<td></td>
<td></td>
<td>127.82</td>
<td>6.60</td>
<td></td>
<td>Mepilex Border Sacrum 282450 [MH]</td>
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</tbody>
</table>

## Dressing Foam with Silicone Heavy Exudate

### Note
Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

<table>
<thead>
<tr>
<th>Max.Qty</th>
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<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td>86.16</td>
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<td></td>
<td>Allevyn Gentle 66800248 [SN]</td>
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<td></td>
<td>Allevyn Gentle Border 66800269 [SN]</td>
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<td>1</td>
<td></td>
<td></td>
<td>43.78</td>
<td>6.60</td>
<td></td>
<td>Mepilex Border 295300 [MH]</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td>33.19</td>
<td>6.60</td>
<td></td>
<td>Mepilex Border 295200 [MH]</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td>39.66</td>
<td>6.60</td>
<td></td>
<td>Mepilex Lite 284100 [MH]</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td>30.84</td>
<td>6.60</td>
<td></td>
<td>Mepilex Lite 284000 [MH]</td>
</tr>
</tbody>
</table>

## Dressing Foam with Silicone Moderate Exudate

### Note
Molnlycke Healthcare products are distributed through leading pharmacy distributors. To ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

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<td>6.60</td>
<td></td>
<td>Mepilex Border 295300 [MH]</td>
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<td></td>
<td>33.19</td>
<td>6.60</td>
<td></td>
<td>Mepilex Border 295200 [MH]</td>
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<tr>
<td>1</td>
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<td></td>
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<td>6.60</td>
<td></td>
<td>Mepilex Lite 284100 [MH]</td>
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<tr>
<td>1</td>
<td></td>
<td></td>
<td>30.84</td>
<td>6.60</td>
<td></td>
<td>Mepilex Lite 284000 [MH]</td>
</tr>
</tbody>
</table>
VARIOUS

Repatriation Pharmaceutical Benefits Scheme

Mohllycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

- **DRESSING FOAM WITH SILVER**
  
  **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.

  **Authority required**
  
  **Wounds**

  **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.

- **DRESSING FOAM WITH SILICONE MODERATE EXUDATE 10 cm x 10 cm dressing, 5**
  
<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>4626L</td>
<td></td>
<td>43.78</td>
<td>6.60</td>
<td></td>
<td>Mepilex 294100 [MH]</td>
</tr>
</tbody>
</table>

- **DRESSING FOAM WITH SILVER 7.5 cm x 7.5 cm dressing, 10**
  
<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>4252T</td>
<td></td>
<td>157.66</td>
<td>6.60</td>
<td></td>
<td>Allevyn Ag Adhesive 66800073 [SN]</td>
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<tbody>
<tr>
<td>4263J</td>
<td></td>
<td>157.66</td>
<td>6.60</td>
<td></td>
<td>Allevyn Ag Gentle Border 66800460 [SN]</td>
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<tr>
<td>4255Y</td>
<td></td>
<td>234.67</td>
<td>6.60</td>
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<td>Allevyn Ag Adhesive 66800075 [SN]</td>
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<tr>
<td>4259E</td>
<td></td>
<td>239.19</td>
<td>6.60</td>
<td></td>
<td>Allevyn Ag Non-Adhesive 66800086 [SN]</td>
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<td>4266M</td>
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<td>234.67</td>
<td>6.60</td>
<td></td>
<td>Allevyn Ag Gentle Border 66800461 [SN]</td>
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<tbody>
<tr>
<td>4258D</td>
<td></td>
<td>291.61</td>
<td>6.60</td>
<td></td>
<td>Allevyn Ag Adhesive 66800078 [SN]</td>
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<tr>
<td>4270R</td>
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<td>291.61</td>
<td>6.60</td>
<td></td>
<td>Allevyn Ag Gentle Border 66800462 [SN]</td>
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</table>

- **DRESSING GAUZE**

  - **DRESSING GAUZE EYE PAD, 12 PADS**
    
    | Max Qty | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
    |---------|-------------|-----------|--------|---------|----------------------------|
    | 4768Y   |             | 17.59     | 6.60   |         | Curity 4112 [KE]           |

- **DRESSING GAUZE ABSORBENT**

  - **DRESSING GAUZE ABSORBENT 10 cm x 10 cm PAD, 100**
    
    | Max Qty | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
    |---------|-------------|-----------|--------|---------|----------------------------|
    | 4708T   |             | 33.35     | 6.60   |         | Handy 711117-06 [BV]       |

  - **DRESSING GAUZE ABSORBENT 5 cm x 5 cm PAD, 100**
    
    | Max Qty | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
    |---------|-------------|-----------|--------|---------|----------------------------|
    | 4707R   |             | 19.62     | 6.60   |         | Handy 711117-05 [BV]       |

- **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...
**VARIOUS**

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 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 agreed pricing from distributors other than those aforementioned.

<table>
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<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>Jelonet 7404 [SN]</td>
<td>1</td>
<td>10</td>
<td>27.43</td>
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### DRESSING GELLING FIBRE

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<tbody>
<tr>
<td>Bactigras 7457 [SN]</td>
<td>1</td>
<td>10</td>
<td>35.01</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

### 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>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
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<tbody>
<tr>
<td>TenderWet 24 Active 609210 [HR]</td>
<td>1</td>
<td>10</td>
<td>83.35</td>
<td>6.60</td>
<td></td>
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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>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>85.21</td>
<td>6.60</td>
<td>TenderWet Active Cavity 609272 [HR]</td>
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</table>

**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 18 cm (foam alternative) dressing, 5**

<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>..</td>
<td>..</td>
<td>110.95</td>
<td>6.60</td>
<td>TenderWet 24 Active 609213 [HR]</td>
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**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 11 cm x 11 cm dressing: island, 10 dressings**

<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>
<td>..</td>
<td>..</td>
<td>71.38</td>
<td>6.60</td>
<td>CombiDERM 651027 [CC]</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>
<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>130.55</td>
<td>6.60</td>
<td>Tielle MTL103 [KI]</td>
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**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 12 cm x 12 cm waterproof pad, 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>
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<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>94.32</td>
<td>6.60</td>
<td>Biatain Adhesive 3420 [CT]</td>
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**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm waterproof pad, 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>‡1</td>
<td>2</td>
<td>..</td>
<td>91.47</td>
<td>6.60</td>
<td>Biatain Adhesive 3423 [CT]</td>
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**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm waterproof pad, 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>
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<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>86.12</td>
<td>6.60</td>
<td>Biatain Non-adhesive 3410 [CT]</td>
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**dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 15 cm waterproof pad, 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>‡1</td>
<td>2</td>
<td>..</td>
<td>84.77</td>
<td>6.60</td>
<td>Biatain Non-adhesive 3413 [CT]</td>
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</table>

**DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE**

*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 Hydroactive Superficial Wound Light Exudate

**Dressing Hydroactive Superficial Wound Light Exudate 5 cm x 6 cm**

<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>73.59</td>
<td>6.60</td>
<td>Allevyn Thin 66047576 [SN]</td>
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**Dressing Hydroactive Superficial Wound Light Exudate 10 cm x 10 cm**

<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>2</td>
<td>1</td>
<td>..</td>
<td>*131.92</td>
<td>6.60</td>
<td>Allevyn Thin 66047578 [SN]</td>
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### Dressing Hydroactive Superficial Wound Moderate Exudate

**Dressing Hydroactive Superficial Wound Moderate Exudate 10 cm x 10 cm**

<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>2</td>
<td>1</td>
<td>..</td>
<td>*99.04</td>
<td>6.60</td>
<td>Cutinova Hydro 66047443 [SN]</td>
</tr>
</tbody>
</table>

---

**Dressing Hydroactive Superficial Wound Moderate Exudate 5 cm x 6 cm**

<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>60.50</td>
<td>6.60</td>
<td>Cutinova Hydro 66047441 [SN]</td>
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</tbody>
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### Dressing Hydrocolloid Cavity Wound

**Dressing Hydrocolloid Cavity Wound Paste, 30 g**

<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>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>..</td>
<td>..</td>
<td>*139.44</td>
<td>6.60</td>
<td>DuoDERM Paste 187930 [CC]</td>
</tr>
</tbody>
</table>

---

### Dressing Hydrocolloid Superficial Wound Light Exudate

**Dressing Hydrocolloid Superficial Wound Light Exudate 10 cm x 10 cm**

<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>71.38</td>
<td>6.60</td>
<td>Comfeel Plus Transparent 3530 [CT]</td>
</tr>
</tbody>
</table>

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**Dressing Hydrocolloid Superficial Wound Light Exudate 5 cm x 7 cm**

<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>42.82</td>
<td>6.60</td>
<td>Comfeel Plus Transparent 3536 [CT]</td>
</tr>
</tbody>
</table>

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**Dressing Hydrocolloid Superficial Wound Light Exudate 9 cm x 14 cm**

<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>83.02</td>
<td>6.60</td>
<td>Comfeel Plus Transparent 3533 [CT]</td>
</tr>
</tbody>
</table>

---

### Dressing Hydrocolloid Superficial Wound Light Exudate

**Dressing Hydrocolloid Superficial Wound Light Exudate 10 cm x 10 cm**

<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>69.62</td>
<td>6.60</td>
<td>Comfeel Plus Transparent 3533 [CT]</td>
</tr>
</tbody>
</table>

---

### Dressing Hydrocolloid Superficial Wound Moderate Exudate

**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 Hydrocolloid Superficial Wound Moderate Exudate 10 cm x 10 cm**

**Dressing Hydrocolloid Superficial Wound Moderate Exudate 5 cm x 6 cm**

**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 Hydrocolloid Superficial Wound Light Exudate**

**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**

**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.

---

**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.

---

**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.

---

**Dressing Hydrocolloid Superficial Wound Light Exudate**

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

---

**Note** Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

---

**Dressing Hydrocolloid Superficial Wound Light Exudate**

**Note** This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

---

**Note** Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.
**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.

### Dressing hydrocolloid superficial wound moderate exudate

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocoll Thin 900758 [HR]</td>
<td>1</td>
<td>49.25</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

### Dressing hydrocolloid superficial wound moderate exudate

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>DuoDERM CGF 187662 [CC]</td>
<td>2</td>
<td>80.18</td>
<td>6.60</td>
<td></td>
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</tbody>
</table>

### Dressing hydrocolloid superficial wound moderate exudate

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Replicare Ultra 6600434 [SN]</td>
<td>1</td>
<td>100.08</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

### Dressing hydrocolloid superficial wound moderate exudate

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocoll 900744 [HR]</td>
<td>1</td>
<td>49.25</td>
<td>6.60</td>
<td></td>
</tr>
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</table>

### Dressing hydrocolloid superficial wound moderate exudate

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>DuoDERM CGF 187660 [CC]</td>
<td>2</td>
<td>214.82</td>
<td>6.60</td>
<td></td>
</tr>
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</table>

### Dressing hydrocolloid superficial wound moderate exudate

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Replicare Ultra 6600434 [SN]</td>
<td>1</td>
<td>100.08</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

### Dressing hydrocolloid superficial wound moderate exudate

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>No. of Rpts</th>
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<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocoll 900936 [HR]</td>
<td>1</td>
<td>87.92</td>
<td>6.60</td>
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### Dressing hydrocolloid superficial wound moderate exudate

<table>
<thead>
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<th>Brand Name and Manufacturer</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfeel Plus Pressure Relieving 3350 [CT]</td>
<td>5</td>
<td>56.29</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

### Dressing hydrocolloid superficial wound moderate exudate

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfeel Plus Ulcer Dressing 3110 [CT]</td>
<td>1</td>
<td>80.73</td>
<td>6.60</td>
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</table>

### Dressing hydrocolloid superficial wound moderate exudate

<table>
<thead>
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<th>Brand Name and Manufacturer</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfeel Plus Pressure Relieving 3353 [CT]</td>
<td>5</td>
<td>60.39</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

### DRESSING HYDROFIBRE ALTERNATE TO ALGINATES

### Dressing hydrofibre alternate to alginates

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquacel Foam Non-Adhesive</td>
<td>10</td>
<td>121.59</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>
### DRESSING HYDROFIBRE WITH SILVER

**Authority required**

**Wounds**

**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>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>Aquacel Extra 420672 [CC]</td>
<td>2797F</td>
<td>1</td>
<td>97.98</td>
<td>6.60</td>
<td></td>
</tr>
<tr>
<td>Aquacel Extra 420673 [CC]</td>
<td>2803M</td>
<td>1</td>
<td>200.52</td>
<td>6.60</td>
<td></td>
</tr>
<tr>
<td>Aquacel Foam Adhesive [CC]</td>
<td>10832D</td>
<td>1</td>
<td>117.94</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>

### DRESSING HYDROGEL

**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>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>DuoDERM Gel H7987 [CC]</td>
<td>4914P</td>
<td>3</td>
<td>*35.25</td>
<td>6.60</td>
<td></td>
</tr>
<tr>
<td>DuoDERM Gel H7987 [CC]</td>
<td>4913N</td>
<td>1</td>
<td>*94.47</td>
<td>6.60</td>
<td></td>
</tr>
</tbody>
</table>
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 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.

### DRESSING HYDROGEL FOAM

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 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.

## Dressing Data

### dressing hydrogel amorphous gel, 10 x 15 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>1</td>
<td>..</td>
<td>64.80</td>
<td>6.60</td>
<td></td>
<td>DuoDERM Gel 187990 [CC]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>..</td>
<td>71.72</td>
<td>6.60</td>
<td></td>
<td>Comfeel Purilon Gel 3900 [CT]</td>
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</tbody>
</table>

### dressing hydrogel amorphous gel, 25 g

<table>
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<tr>
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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>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>3</td>
<td>..</td>
<td>*78.58</td>
<td>6.60</td>
<td></td>
<td>Intrasite Gel 7313 [SN]</td>
</tr>
</tbody>
</table>

### dressing hydrogel amorphous gel, 50 g

<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>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>3</td>
<td>..</td>
<td>*38.37</td>
<td>6.60</td>
<td></td>
<td>SoloSite Gel 36361338 [SN]</td>
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</table>

### dressing hydrogel foam 10 cm x 10 cm dressing, 10

<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>125.57</td>
<td>6.60</td>
<td></td>
<td>Sorbact Foam Dressing S98310 [YB]</td>
</tr>
</tbody>
</table>

### dressing hydrogel ribbon 1 cm x 50 cm dressing, 20

<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>187.65</td>
<td>6.60</td>
<td></td>
<td>Sorbact Ribbon Gauze S98118 [YB]</td>
</tr>
</tbody>
</table>

### dressing hydrogel ribbon 5 cm x 200 cm dressing, 10

<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>185.39</td>
<td>6.60</td>
<td></td>
<td>Sorbact Ribbon Gauze S98120 [YB]</td>
</tr>
</tbody>
</table>

### dressing hydrogel sheet 9.5 cm x 10.2 cm dressing, 5

<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>2</td>
<td>..</td>
<td>..</td>
<td>*81.82</td>
<td>6.60</td>
<td></td>
<td>Nu-Gel 2497 [KI]</td>
</tr>
</tbody>
</table>

### dressing hydrogel sheet 10 cm x 10 cm dressing, 5

<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>2</td>
<td>..</td>
<td>..</td>
<td>*54.38</td>
<td>6.60</td>
<td></td>
<td>Hydrosorb 900854 [HR]</td>
</tr>
</tbody>
</table>

Repatriation Pharmaceutical Benefits Scheme 1041
### DRESSING HYDROPHOBIC

<table>
<thead>
<tr>
<th>Dressing Description</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>
</tr>
</thead>
<tbody>
<tr>
<td>Dressing hydrophobic 15 cm x 15 cm foam dressing, 10</td>
<td>1</td>
<td>..</td>
<td>204.59</td>
<td>6.60</td>
<td>Sorbact Foam Dressing S98315 [YB]</td>
<td></td>
</tr>
<tr>
<td>Dressing hydrophobic 10 cm x 10 cm dressing, 10</td>
<td>1</td>
<td>..</td>
<td>198.94</td>
<td>6.60</td>
<td>Sorbact Foam Gentle Border 98532 [YB]</td>
<td></td>
</tr>
<tr>
<td>Dressing hydrophobic 10 cm x 10 cm dressing, 10</td>
<td>1</td>
<td>..</td>
<td>89.97</td>
<td>6.60</td>
<td>Sorbact Superabsorbent 98501 [YB]</td>
<td></td>
</tr>
<tr>
<td>Dressing hydrophobic 15 cm x 15 cm dressing, 10</td>
<td>1</td>
<td>..</td>
<td>311.84</td>
<td>6.60</td>
<td>Sorbact Foam Gentle Border 98533 [YB]</td>
<td></td>
</tr>
<tr>
<td>Dressing hydrophobic 20 cm x 20 cm dressing, 10</td>
<td>1</td>
<td>..</td>
<td>244.10</td>
<td>6.60</td>
<td>Sorbact Superabsorbent 98503 [YB]</td>
<td></td>
</tr>
</tbody>
</table>

### DRESSING NON ADHERENT

**Note** Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email 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>Dressing Description</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>
</tr>
</thead>
<tbody>
<tr>
<td>Dressing non adherent 7.5 cm x 10 cm dressing, 10</td>
<td>1</td>
<td>..</td>
<td>64.02</td>
<td>6.60</td>
<td>Mepitel 290510 [MH]</td>
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</tr>
<tr>
<td>Dressing non adherent 7.5 cm x 10 cm dressing, 10</td>
<td>1</td>
<td>..</td>
<td>104.02</td>
<td>6.60</td>
<td>Mepitel 290710 [MH]</td>
<td></td>
</tr>
<tr>
<td>Dressing non adherent 5 cm x 5 cm dressing, 5</td>
<td>2</td>
<td>..</td>
<td>19.69</td>
<td>6.60</td>
<td>Atrauman 499513 [HR]</td>
<td></td>
</tr>
<tr>
<td>Dressing non adherent 10 cm x 10 cm dressing, 10</td>
<td>1</td>
<td>..</td>
<td>41.27</td>
<td>6.60</td>
<td>Melolin 66974933 [SN]</td>
<td></td>
</tr>
<tr>
<td>Dressing non adherent 10 cm x 10 cm dressing, 5</td>
<td>2</td>
<td>..</td>
<td>30.22</td>
<td>6.60</td>
<td>Cutilin Non-Stick Wound Pad 36361375 [SN]</td>
<td></td>
</tr>
<tr>
<td>Dressing non adherent 5 cm x 5 cm dressing, 5</td>
<td>2</td>
<td>..</td>
<td>20.98</td>
<td>6.60</td>
<td>Cutilin Non-Stick Wound Pad 36361374 [SN]</td>
<td></td>
</tr>
</tbody>
</table>
## DRESSING NON-ADHERENT ABSORBENT

<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>2</td>
<td>..</td>
<td>..</td>
<td><strong>22.48</strong></td>
<td>6.60</td>
<td>Melolin 36361357 [SN]</td>
</tr>
</tbody>
</table>

### dressing non-adherent absorbent 12.5 cm x 12.5 cm hydroactive dressing, 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>..</td>
<td>26.21</td>
<td>6.60</td>
<td>Vliwasorb Pro 32641 [LC]</td>
</tr>
</tbody>
</table>

### dressing non-adherent absorbent 22 cm x 22 cm hydroactive dressing, 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>..</td>
<td>37.07</td>
<td>6.60</td>
<td>Vliwasorb Pro 32643 [LC]</td>
</tr>
</tbody>
</table>

### dressing non-adherent absorbent 22 cm x 32 cm hydroactive dressing, 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>..</td>
<td>49.65</td>
<td>6.60</td>
<td>Vliwasorb Pro 32644 [LC]</td>
</tr>
</tbody>
</table>

## DRESSING NON-ADHERENT WITH SILICONE

<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>..</td>
<td>308.67</td>
<td>6.60</td>
<td>Mepitel One 289500 [MH]</td>
</tr>
</tbody>
</table>

### dressing non-adherent with silicone 10 cm x 18 cm dressing, 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>..</td>
<td>91.69</td>
<td>6.60</td>
<td>Mepitel One 289100 [MH]</td>
</tr>
</tbody>
</table>

## DRESSING TULLE NON GAUZE PARAFFIN

<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>10</td>
<td>1</td>
<td>..</td>
<td><strong>20.14</strong></td>
<td>6.60</td>
<td>Adaptic 2012 [KI]</td>
</tr>
</tbody>
</table>

## DRESSING WITH SILVER

**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.

### Authority required

**Wounds**

**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.

### dressing with silver 12.5 cm x 12.5 cm hydroactive dressing, 5

<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>..</td>
<td>183.48</td>
<td>6.60</td>
<td>Biatain Ag 9632 [CT]</td>
</tr>
</tbody>
</table>

### dressing with silver 10 cm x 10 cm hydroactive dressing, 5

<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>..</td>
<td>168.77</td>
<td>6.60</td>
<td>Biatain Ag 9622 [CT]</td>
</tr>
</tbody>
</table>

## DRESSING WITH SILVER

**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.

### Authority required

**Wounds**

**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.

### dressing with silver 10 cm x 10 cm tulle dressing, 3

<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>..</td>
<td>44.88</td>
<td>6.60</td>
<td>Atrauman Ag 499572 [HR]</td>
</tr>
</tbody>
</table>
### GAUZE AND COTTON TISSUE COMBINE ROLL

<table>
<thead>
<tr>
<th>Item Description</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>
</tr>
</thead>
<tbody>
<tr>
<td>Gauze and cotton tissue combine roll 10 cm x 10 m wrapped pack roll, 1</td>
<td>1</td>
<td></td>
<td>21.40</td>
<td>6.60</td>
<td></td>
<td>JJ 12010 [JJ]</td>
</tr>
</tbody>
</table>

### PAD WOUND DEBRIDEMENT

Note: If the wound has not healed during this period, further use is to be discontinued after initial pack, no repeats. Where wounds remain unresponsive to standard treatment, patient should be referred on to a specialist.

<table>
<thead>
<tr>
<th>Item Description</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>
</tr>
</thead>
<tbody>
<tr>
<td>Pad wound debridement 10 cm x 10 cm pad, 5</td>
<td>1</td>
<td></td>
<td>92.39</td>
<td>6.60</td>
<td></td>
<td>Debrisoft [LC]</td>
</tr>
</tbody>
</table>

### Povidone-Iodine

<table>
<thead>
<tr>
<th>Item Description</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>
</tr>
</thead>
<tbody>
<tr>
<td>Povidone-iodine 9.5 cm x 9.5 cm dressing, 25</td>
<td>1</td>
<td>2</td>
<td>78.57</td>
<td>6.60</td>
<td></td>
<td>Inadine [KI]</td>
</tr>
</tbody>
</table>

### Sodium Chloride + Hypochlorous Acid + Sodium Hypochlorite

<table>
<thead>
<tr>
<th>Item Description</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>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride 0.022% + hypochlorous acid 0.004% + sodium hypochlorite 0.004% irrigation solution, 250 mL</td>
<td>1</td>
<td>3</td>
<td>31.37</td>
<td>6.60</td>
<td></td>
<td>Microdacyn [TF]</td>
</tr>
</tbody>
</table>

### Tape Non Woven Retention Polyacrylate

<table>
<thead>
<tr>
<th>Item Description</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>
</tr>
</thead>
<tbody>
<tr>
<td>Tape non woven retention polyacrylate 2.5 cm x 9.1 m tape, 1 roll</td>
<td>1</td>
<td></td>
<td>17.63</td>
<td>6.60</td>
<td></td>
<td>Medipore 2961 [MM]</td>
</tr>
</tbody>
</table>

### Tap Non Woven Retention Polyacrylate

Note: Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

<table>
<thead>
<tr>
<th>Item Description</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>
</tr>
</thead>
<tbody>
<tr>
<td>Tape non woven retention polyacrylate 2.5 cm x 10 m tape, 1 roll</td>
<td>1</td>
<td></td>
<td>16.04</td>
<td>6.60</td>
<td></td>
<td>Mefix 310250 [MH]</td>
</tr>
</tbody>
</table>

### Tape Plaster Adhesive Elastic

<table>
<thead>
<tr>
<th>Item Description</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>
</tr>
</thead>
<tbody>
<tr>
<td>Tape plaster adhesive elastic 2.5 cm x 2.5 m tape, 1 roll</td>
<td>1</td>
<td></td>
<td>18.55</td>
<td>6.60</td>
<td></td>
<td>Leukoplast 01071-00 [BV]</td>
</tr>
</tbody>
</table>

### Tape Plaster Adhesive Elastic

<table>
<thead>
<tr>
<th>Item Description</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>
</tr>
</thead>
<tbody>
<tr>
<td>Tape plaster adhesive elastic 5 cm x 2.5 m tape, 1 roll</td>
<td>1</td>
<td></td>
<td>24.49</td>
<td>6.60</td>
<td></td>
<td>Leukoplast 01072-00 [BV]</td>
</tr>
</tbody>
</table>

### Tape Plaster Adhesive Elastic

<table>
<thead>
<tr>
<th>Item Description</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>
</tr>
</thead>
<tbody>
<tr>
<td>Tape plaster adhesive hypoallergenic 1.9 cm x 5.4 m dispenser tape, 1 roll</td>
<td>1</td>
<td></td>
<td>16.05</td>
<td>6.60</td>
<td></td>
<td>Nexcare Durable Cloth First Aid Tape 799 [MM]</td>
</tr>
</tbody>
</table>
tape plaster adhesive hypoallergenic 1.9 cm x 7.3 m dispenser tape, 1 roll
4849F

<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>16.05</td>
<td>6.60</td>
<td></td>
<td>Nexcare Gentle Paper First Aid Tape 789 [MM]</td>
</tr>
</tbody>
</table>

tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll
4783R

<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>15.96</td>
<td>6.60</td>
<td></td>
<td>Leukopor 2471 [BV]</td>
</tr>
</tbody>
</table>

tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll
4785W

<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>16.25</td>
<td>6.60</td>
<td></td>
<td>Leukosilk 1021 [BV]</td>
</tr>
</tbody>
</table>

tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll
4787Y

<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>18.90</td>
<td>6.60</td>
<td></td>
<td>Leukosilk 1022 [BV]</td>
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</tbody>
</table>

tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll
4794H

<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>18.37</td>
<td>6.60</td>
<td></td>
<td>Leukopor 2472 [BV]</td>
</tr>
</tbody>
</table>

tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll
4788B

<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>21.40</td>
<td>6.60</td>
<td></td>
<td>Leukoflex 1124 [BV]</td>
</tr>
</tbody>
</table>

tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll
4789C

<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>22.72</td>
<td>6.60</td>
<td></td>
<td>Leukosilk 1024 [BV]</td>
</tr>
</tbody>
</table>

tape plaster adhesive hypoallergenic 5 cm x 5 m tape, 1 roll
4790D

<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>21.89</td>
<td>6.60</td>
<td></td>
<td>Leukopor 2474 [BV]</td>
</tr>
</tbody>
</table>

**TAPE PLASTER ADHESIVE WITH SILICONE**

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tape plaster adhesive with silicone 2 cm x 3 m tape, 1 roll
4239D

<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>25.02</td>
<td>6.60</td>
<td></td>
<td>Mepitac 298300 [MH]</td>
</tr>
</tbody>
</table>

tape plaster adhesive with silicone 4 cm x 1.5 m tape, 1 roll
4240E

<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>25.02</td>
<td>6.60</td>
<td></td>
<td>Mepitac 298400 [MH]</td>
</tr>
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</table>
Extemporaneously Prepared Benefits
## Drug Tariff

<table>
<thead>
<tr>
<th>Drug</th>
<th>Standard</th>
<th>Recovery Prices</th>
<th>0.1 g/mL</th>
<th>1 g/mL</th>
<th>10 g/mL</th>
<th>100 g/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acacia Mucilage (by weight)</td>
<td>APF 15</td>
<td></td>
<td>0.01</td>
<td>0.11</td>
<td>0.87</td>
<td>7.77</td>
</tr>
<tr>
<td>Acacia, powdered</td>
<td>BP</td>
<td></td>
<td>0.02</td>
<td>0.19</td>
<td>1.55</td>
<td>13.82</td>
</tr>
<tr>
<td>Acetic Acid (33 per cent)</td>
<td>BP</td>
<td></td>
<td>0.01</td>
<td>0.06</td>
<td>0.47</td>
<td>4.20</td>
</tr>
<tr>
<td>Acetic Acid (6 per cent)</td>
<td>BP</td>
<td></td>
<td>0.01</td>
<td>0.02</td>
<td>0.16</td>
<td>1.47</td>
</tr>
<tr>
<td>Acetic Acid Glacial BP</td>
<td>BP</td>
<td></td>
<td>0.02</td>
<td>0.14</td>
<td>1.10</td>
<td>9.76</td>
</tr>
<tr>
<td>Acetone (use as additive only)</td>
<td>BP</td>
<td></td>
<td>0.02</td>
<td>0.19</td>
<td>1.52</td>
<td>13.48</td>
</tr>
<tr>
<td>Alum</td>
<td>BP</td>
<td></td>
<td>0.01</td>
<td>0.08</td>
<td>0.60</td>
<td>5.32</td>
</tr>
<tr>
<td>Aluminium Acetate Solution</td>
<td>BP</td>
<td></td>
<td>0.02</td>
<td>0.17</td>
<td>1.38</td>
<td>12.27</td>
</tr>
<tr>
<td>Anise Oil BP</td>
<td>BP</td>
<td></td>
<td>0.18</td>
<td>1.44</td>
<td>11.52</td>
<td>102.44</td>
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<tr>
<td>Anise Water Concentrated 1 in 40</td>
<td>BP</td>
<td></td>
<td>0.01</td>
<td>0.08</td>
<td>0.60</td>
<td>5.33</td>
</tr>
<tr>
<td>Aqueous Cream (for use only as a base combined with active ingredients)</td>
<td>APF</td>
<td></td>
<td>0.01</td>
<td>0.05</td>
<td>0.39</td>
<td>3.43</td>
</tr>
<tr>
<td>Ascorbic Acid (for use only as an ingredient of ferrous sulfate mixtures)</td>
<td>BP</td>
<td></td>
<td>0.39</td>
<td>3.14</td>
<td>25.11</td>
<td>223.22</td>
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<tr>
<td>Aspirin</td>
<td>BP</td>
<td></td>
<td>0.19</td>
<td>1.51</td>
<td>12.09</td>
<td>107.43</td>
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<tr>
<td>Belladonna Tincture</td>
<td>BP</td>
<td></td>
<td>0.20</td>
<td>1.59</td>
<td>12.74</td>
<td>113.26</td>
</tr>
<tr>
<td>Benzoic Acid BP</td>
<td>BP</td>
<td></td>
<td>0.14</td>
<td>1.14</td>
<td>9.11</td>
<td>80.98</td>
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<tr>
<td>Benzoic Acid Compound Ointment</td>
<td>APF</td>
<td></td>
<td>0.02</td>
<td>0.19</td>
<td>1.48</td>
<td>13.12</td>
</tr>
<tr>
<td>Benzoic Acid Solution</td>
<td>BP</td>
<td></td>
<td>0.02</td>
<td>0.14</td>
<td>1.15</td>
<td>10.24</td>
</tr>
<tr>
<td>Benzoic Acid Compound Tincture</td>
<td>BP</td>
<td></td>
<td>0.07</td>
<td>0.56</td>
<td>4.50</td>
<td>39.98</td>
</tr>
<tr>
<td>Boric Acid (use as additive only)</td>
<td>BP</td>
<td></td>
<td>0.02</td>
<td>0.17</td>
<td>1.38</td>
<td>12.30</td>
</tr>
<tr>
<td>Boric Acid, Olive Oil and Zinc Oxide Ointment</td>
<td>OGH</td>
<td></td>
<td>0.02</td>
<td>0.14</td>
<td>0.96</td>
<td>8.12</td>
</tr>
<tr>
<td>Calcium Hydroxide</td>
<td>BP</td>
<td></td>
<td>0.12</td>
<td>0.94</td>
<td>7.54</td>
<td>67.02</td>
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<tr>
<td>Calcium Hydroxide Solution</td>
<td>BP</td>
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<td>0.01</td>
<td>0.03</td>
<td>0.20</td>
<td>1.80</td>
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<tr>
<td>Castor Oil (use as additive only)</td>
<td>BP</td>
<td></td>
<td>0.02</td>
<td>0.16</td>
<td>1.24</td>
<td>11.03</td>
</tr>
<tr>
<td>Cetomacrogol Aqueous Cream (for use only as a base combined with active ingredients)</td>
<td>APF</td>
<td></td>
<td>0.01</td>
<td>0.05</td>
<td>0.42</td>
<td>3.70</td>
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<td>Cetrimide Aqueous Cream (for use only as a base combined with active ingredients)</td>
<td>APF</td>
<td></td>
<td>0.02</td>
<td>0.17</td>
<td>1.37</td>
<td>12.21</td>
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<tr>
<td>Chlorhexidine Acetate (use as additive only)</td>
<td>BP</td>
<td></td>
<td>0.63</td>
<td>5.03</td>
<td>40.21</td>
<td>357.42</td>
</tr>
<tr>
<td>Chlorhexidine Aqueous Cream (for use only as a base combined with active ingredients)</td>
<td>APF</td>
<td></td>
<td>0.03</td>
<td>0.24</td>
<td>1.95</td>
<td>17.36</td>
</tr>
<tr>
<td>Chloroform (use as additive only)</td>
<td>BP</td>
<td></td>
<td>0.10</td>
<td>0.80</td>
<td>6.37</td>
<td>56.63</td>
</tr>
<tr>
<td>Chloroform Spirit</td>
<td>BP</td>
<td></td>
<td>0.01</td>
<td>0.09</td>
<td>0.74</td>
<td>6.62</td>
</tr>
<tr>
<td>Chloroform Water Concentrated 1 in 40</td>
<td>APF 15</td>
<td></td>
<td>0.02</td>
<td>0.12</td>
<td>0.93</td>
<td>8.29</td>
</tr>
<tr>
<td>Citric Acid Monohydrate</td>
<td>BP</td>
<td></td>
<td>0.04</td>
<td>0.30</td>
<td>2.40</td>
<td>21.30</td>
</tr>
<tr>
<td>Coal Tar</td>
<td>BP</td>
<td></td>
<td>0.32</td>
<td>2.54</td>
<td>20.30</td>
<td>180.45</td>
</tr>
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<td>Coal Tar Solution</td>
<td>BP</td>
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<td>0.02</td>
<td>0.19</td>
<td>1.55</td>
<td>13.78</td>
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<tr>
<td>Cocaine Hydrochloride</td>
<td>BP</td>
<td></td>
<td>5.81</td>
<td>46.47</td>
<td>371.74</td>
<td>3304.35</td>
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<tr>
<td>Coconut Oil</td>
<td>BP</td>
<td></td>
<td>0.01</td>
<td>0.05</td>
<td>0.36</td>
<td>3.23</td>
</tr>
<tr>
<td>Codeine Linctus</td>
<td>APF</td>
<td></td>
<td>0.02</td>
<td>0.13</td>
<td>1.04</td>
<td>9.25</td>
</tr>
<tr>
<td>Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children)</td>
<td>BP</td>
<td></td>
<td>2.88</td>
<td>23.07</td>
<td>184.56</td>
<td>1640.50</td>
</tr>
<tr>
<td>Collodion Flexible</td>
<td>BP</td>
<td></td>
<td>0.20</td>
<td>1.57</td>
<td>12.54</td>
<td>111.51</td>
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<tr>
<td>Dithranol</td>
<td>BP</td>
<td></td>
<td>5.03</td>
<td>40.20</td>
<td>321.56</td>
<td>2858.28</td>
</tr>
<tr>
<td>Emulsifying Ointment (for use only as a base combined with active ingredients)</td>
<td>BP</td>
<td></td>
<td>0.02</td>
<td>0.16</td>
<td>1.26</td>
<td>11.16</td>
</tr>
<tr>
<td>Ephedrine Hydrochloride (may only be prescribed in nasal instillations)</td>
<td>BP</td>
<td></td>
<td>2.61</td>
<td>20.90</td>
<td>167.21</td>
<td>1486.33</td>
</tr>
<tr>
<td>Ethanol (90 per cent) (use as additive only)</td>
<td>BP</td>
<td></td>
<td>0.01</td>
<td>0.04</td>
<td>0.31</td>
<td>2.77</td>
</tr>
<tr>
<td>Ethanol (96 per cent) (use as additive only)</td>
<td>BP</td>
<td></td>
<td>0.01</td>
<td>0.06</td>
<td>0.44</td>
<td>3.90</td>
</tr>
<tr>
<td>Drug</td>
<td>Standard</td>
<td>Recovery Prices</td>
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<td>---------------------------------------------------------------------</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>0.1 g/mL $</td>
<td>1 g/mL $</td>
<td>10 g/mL $</td>
<td>100 g/mL $</td>
<td></td>
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<tr>
<td>Ether Solvent (use as additive only)</td>
<td>BP 0.29</td>
<td>2.35</td>
<td>18.83</td>
<td>167.36</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eucalyptus Oil (use as additive only)</td>
<td>BP 0.03</td>
<td>0.21</td>
<td>1.68</td>
<td>14.96</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ferrous Sulfate</td>
<td>BP 0.05</td>
<td>0.40</td>
<td>3.19</td>
<td>28.38</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formaldehyde Solution</td>
<td>BP 0.07</td>
<td>0.53</td>
<td>4.26</td>
<td>37.86</td>
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<tr>
<td>Gentian Alkaline Mixture</td>
<td>APF 0.01</td>
<td>0.09</td>
<td>0.68</td>
<td>6.00</td>
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<tr>
<td>Glycerol</td>
<td>BP 0.02</td>
<td>0.13</td>
<td>1.04</td>
<td>9.26</td>
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<tr>
<td>Honey Purified (use as additive only)</td>
<td>BP 1993</td>
<td>0.01</td>
<td>0.27</td>
<td>2.44</td>
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<tr>
<td>Hydroxybenzoate Compound Solution</td>
<td>APF 0.09</td>
<td>0.68</td>
<td>5.42</td>
<td>48.17</td>
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<tr>
<td>Iodine</td>
<td>BP 0.34</td>
<td>2.72</td>
<td>21.79</td>
<td>193.72</td>
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<td></td>
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<tr>
<td>Iodine Alcoholic Solution</td>
<td>BP 0.04</td>
<td>0.32</td>
<td>2.59</td>
<td>22.99</td>
<td></td>
<td></td>
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<tr>
<td>Iodine Aqueous Oral Solution</td>
<td>BP 0.04</td>
<td>0.33</td>
<td>2.62</td>
<td>23.27</td>
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</tr>
<tr>
<td>Kaolin Mixture</td>
<td>BPC 0.03</td>
<td>0.25</td>
<td>1.99</td>
<td>17.68</td>
<td></td>
<td></td>
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<tr>
<td>Kaolin and Opium Mixture</td>
<td>APF 14</td>
<td>0.01</td>
<td>0.10</td>
<td>0.82</td>
<td>7.27</td>
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<tr>
<td>Lactic Acid</td>
<td>BP 0.38</td>
<td>3.02</td>
<td>24.13</td>
<td>214.48</td>
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</tr>
<tr>
<td>Lavender Spike Oil</td>
<td>BPC 0.13</td>
<td>1.04</td>
<td>8.32</td>
<td>73.91</td>
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<tr>
<td>Liqueurc Liquid Extract</td>
<td>BP 0.03</td>
<td>0.23</td>
<td>1.84</td>
<td>16.37</td>
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</tr>
<tr>
<td>Magnesium Carbonate Light</td>
<td>BP 0.05</td>
<td>0.37</td>
<td>2.92</td>
<td>25.99</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium Sulfate (may only be prescribed for other than oral use)</td>
<td>BP 0.01</td>
<td>0.04</td>
<td>0.29</td>
<td>2.60</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium Trisilicate</td>
<td>BP 0.06</td>
<td>0.44</td>
<td>3.52</td>
<td>31.25</td>
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<td></td>
</tr>
<tr>
<td>Menthol, Racemic or Levomenthol</td>
<td>BP 0.28</td>
<td>2.24</td>
<td>17.94</td>
<td>159.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methyl Hydroxybenzoate</td>
<td>BP 0.46</td>
<td>3.71</td>
<td>29.71</td>
<td>264.11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methyl Hydroxybenzoate Solution</td>
<td>APF 0.05</td>
<td>0.38</td>
<td>3.05</td>
<td>27.09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methylated Industrial Spirit (use as additive only)</td>
<td>BP 0.01</td>
<td>0.02</td>
<td>0.12</td>
<td>1.04</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Olive Oil (use as additive only)</td>
<td>BP 0.02</td>
<td>0.13</td>
<td>1.05</td>
<td>9.32</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paraffin Hard</td>
<td>BP 0.06</td>
<td>0.49</td>
<td>3.91</td>
<td>34.76</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paraffin Light Liquid</td>
<td>BP 0.02</td>
<td>0.17</td>
<td>1.39</td>
<td>12.32</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paraffin Liquid (use as additive only)</td>
<td>BP 0.01</td>
<td>0.08</td>
<td>0.60</td>
<td>5.34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paraffin Soft White</td>
<td>BP 0.01</td>
<td>0.06</td>
<td>0.49</td>
<td>4.37</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paraffin Soft Yellow</td>
<td>BP 0.01</td>
<td>0.05</td>
<td>0.42</td>
<td>3.75</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peppermint Oil (use as additive only)</td>
<td>BP 0.08</td>
<td>0.66</td>
<td>5.28</td>
<td>46.92</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peppermint Water Concentrated 1 in 40 (use as additive only)</td>
<td>APF 16</td>
<td>0.04</td>
<td>0.31</td>
<td>2.48</td>
<td>22.05</td>
<td></td>
</tr>
<tr>
<td>Phenobarbital Sodium (may only be prescribed for the treatment of epilepsy)</td>
<td>BP 9.37</td>
<td>74.92</td>
<td>599.36</td>
<td>5327.61</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phenol Liquefied (not available for ear drops)</td>
<td>BP 0.26</td>
<td>2.08</td>
<td>16.60</td>
<td>147.57</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Podophyllum Resin</td>
<td>BP 4.55</td>
<td>36.41</td>
<td>291.31</td>
<td>2589.44</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potassium Citrate</td>
<td>BP 0.03</td>
<td>0.22</td>
<td>1.79</td>
<td>15.92</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potassium Iodide</td>
<td>BP 0.47</td>
<td>3.79</td>
<td>30.28</td>
<td>269.13</td>
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<td></td>
</tr>
<tr>
<td>Potassium Permanganate</td>
<td>BP 0.06</td>
<td>0.50</td>
<td>4.01</td>
<td>35.65</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propyl Hydroxybenzoate</td>
<td>BP 0.42</td>
<td>3.36</td>
<td>26.91</td>
<td>239.22</td>
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<td></td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>BP 0.02</td>
<td>0.12</td>
<td>0.96</td>
<td>8.52</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Red Syrup</td>
<td>APF 15</td>
<td>0.02</td>
<td>0.13</td>
<td>1.04</td>
<td>9.23</td>
<td></td>
</tr>
<tr>
<td>Resorcinol</td>
<td>BP 0.45</td>
<td>3.57</td>
<td>28.59</td>
<td>254.15</td>
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</tr>
<tr>
<td>Salicylic Acid</td>
<td>BP 0.04</td>
<td>0.33</td>
<td>2.64</td>
<td>23.49</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salicylic Acid Ointment</td>
<td>APF 0.02</td>
<td>0.17</td>
<td>1.38</td>
<td>12.23</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salicylic Acid Ointment</td>
<td>BP 0.02</td>
<td>0.17</td>
<td>1.38</td>
<td>12.23</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Simple Ointment (white) (for use only as a base combined with active ingredients)</td>
<td>BP 0.02</td>
<td>0.14</td>
<td>1.11</td>
<td>9.88</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Simple Ointment (yellow) (for use only as a base combined with active ingredients)</td>
<td>BP 0.02</td>
<td>0.14</td>
<td>1.11</td>
<td>9.88</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium Bicarbonate</td>
<td>BP 0.03</td>
<td>0.21</td>
<td>1.65</td>
<td>14.65</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>BP 0.03</td>
<td>0.20</td>
<td>1.57</td>
<td>13.94</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium Chloride Solution</td>
<td>BP 0.01</td>
<td>0.02</td>
<td>0.12</td>
<td>1.04</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium Citrate</td>
<td>BP 0.07</td>
<td>0.56</td>
<td>4.45</td>
<td>39.54</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium Thiosulfate (use as additive only)</td>
<td>BP 0.05</td>
<td>0.40</td>
<td>3.20</td>
<td>28.46</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Starch</td>
<td>BP 0.02</td>
<td>0.12</td>
<td>0.95</td>
<td>8.49</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sulfur Ointment (for use only as a base combined with active ingredients)</td>
<td>BP 1980</td>
<td>0.02</td>
<td>0.16</td>
<td>1.24</td>
<td>10.99</td>
<td></td>
</tr>
<tr>
<td>Sulfur Precipitated</td>
<td>BP 1980</td>
<td>0.03</td>
<td>0.26</td>
<td>2.09</td>
<td>18.57</td>
<td></td>
</tr>
<tr>
<td>Syrup</td>
<td>BP 0.01</td>
<td>0.06</td>
<td>0.47</td>
<td>4.16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Talc Purified, sterilised</td>
<td>BP 0.07</td>
<td>0.52</td>
<td>4.13</td>
<td>36.71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thymol</td>
<td>BP 0.56</td>
<td>4.44</td>
<td>35.51</td>
<td>315.66</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thymol Compound Mouth Wash</td>
<td>APF 15</td>
<td>0.02</td>
<td>0.13</td>
<td>1.06</td>
<td>9.40</td>
<td></td>
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## Standard Formula Preparations

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<td>Salicylic Acid and Sulfur Aqueous APF</td>
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<td>Dusting Powders (Maximum Quantity 100 g and 1 Repeat)</td>
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<td>Kaolin BPC 1968</td>
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<td>7326E</td>
<td>Paints (Maximum Quantity 25 ml and 1 Repeat)</td>
<td>Salicylic Acid APF</td>
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## Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits

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