Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 December 2018
## Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 December 2018 and are included, where applicable, in prices published in the Schedule —

<table>
<thead>
<tr>
<th>Fees</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dispensing Fees:</strong></td>
<td></td>
</tr>
<tr>
<td>Ready-prepared</td>
<td>$7.29</td>
</tr>
<tr>
<td>Dangerous drug fee</td>
<td>$3.07</td>
</tr>
<tr>
<td>Extemporaneously-prepared</td>
<td>$9.33</td>
</tr>
<tr>
<td>Allowable additional patient charge*</td>
<td>$4.45</td>
</tr>
<tr>
<td><strong>Additional Fees (for safety net prices):</strong></td>
<td></td>
</tr>
<tr>
<td>Ready-prepared</td>
<td>$1.23</td>
</tr>
<tr>
<td>Extemporaneously-prepared</td>
<td>$1.59</td>
</tr>
<tr>
<td><strong>Patient Co-payments:</strong></td>
<td></td>
</tr>
<tr>
<td>General</td>
<td>$39.50</td>
</tr>
<tr>
<td>Concessional</td>
<td>$6.40</td>
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<tr>
<td><strong>Safety Net Thresholds:</strong></td>
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<tr>
<td>General</td>
<td>$1521.80</td>
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<tr>
<td>Concessional</td>
<td>$384.00</td>
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<tr>
<td><strong>Safety Net Card Issue Fee:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>$9.91</td>
</tr>
</tbody>
</table>

*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 2018. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag
Deletions

Deletion – Item

10016E  BENZATROPINE, benztropine mesilate 2 mg/2 mL injection, 10 x 2 mL vials (Benztropine Omega)

Alterations

Alteration – Item Description

From 3489P  METHOXYFLURANE, methoxyflurane 999.9 mg/g inhalation solution, 3 mL (Pentrox)
To 3489P  METHOXYFLURANE, methoxyflurane 99.9% (999 mg/g) inhalation solution, 3 mL bottle (Pentrox)

General Pharmaceutical Benefits
Additions

Addition – Item

11559J  CLONAZEPAM, clonazepam 500 microgram tablet, 50 (Rivotril)
11577H  ERTUGLIFLOZIN, ertugliflozin 5 mg tablet, 28 (Steglatro 5)
11585R  ERTUGLIFLOZIN, ertugliflozin 5 mg tablet, 28 (Steglatro 5)
11570Y  ERTUGLIFLOZIN, ertugliflozin 15 mg tablet, 28 (Steglatro 15)
11571B  ERTUGLIFLOZIN, ertugliflozin 15 mg tablet, 28 (Steglatro 15)
11564P  ERTUGLIFLOZIN + METFORMIN, ertugliflozin 2.5 mg + metformin hydrochloride 1 g tablet, 56 (Segluromet 2.5/1000)
11581M  ERTUGLIFLOZIN + METFORMIN, ertugliflozin 2.5 mg + metformin hydrochloride 1 g tablet, 56 (Segluromet 2.5/1000)
11575F  ERTUGLIFLOZIN + METFORMIN, ertugliflozin 2.5 mg + metformin hydrochloride 500 mg tablet, 56 (Segluromet 2.5/500)
11584Q  ERTUGLIFLOZIN + METFORMIN, ertugliflozin 2.5 mg + metformin hydrochloride 500 mg tablet, 56 (Segluromet 2.5/500)
11563N  ERTUGLIFLOZIN + METFORMIN, ertugliflozin 7.5 mg + metformin hydrochloride 1 g tablet, 56 (Segluromet 7.5/1000)
11569X  ERTUGLIFLOZIN + METFORMIN, ertugliflozin 7.5 mg + metformin hydrochloride 1 g tablet, 56 (Segluromet 7.5/1000)
11562M  ERTUGLIFLOZIN + METFORMIN, ertugliflozin 7.5 mg + metformin hydrochloride 500 mg tablet, 56 (Segluromet 7.5/500)
11568W  ERTUGLIFLOZIN + METFORMIN, ertugliflozin 7.5 mg + metformin hydrochloride 500 mg tablet, 56 (Segluromet 7.5/500)
11561L  ERTUGLIFLOZIN + SITAGLIPTIN, ertugliflozin 5 mg + sitagliptin 100 mg tablet, 28 (Steglujan 5/100)
ERTUGLIFLOZIN + SITAGLIPTIN, ertugliflozin 5 mg + sitagliptin 100 mg tablet, 28 (Steglujan 5/100)
ERTUGLIFLOZIN + SITAGLIPTIN, ertugliflozin 15 mg + sitagliptin 100 mg tablet, 28 (Steglujan 15/100)
ERTUGLIFLOZIN + SITAGLIPTIN, ertugliflozin 15 mg + sitagliptin 100 mg tablet, 28 (Steglujan 15/100)
ERTUGLIFLOZIN + SITAGLIPTIN, ertugliflozin 5 mg + sitagliptin 100 mg tablet, 28 (Steglujan 5/100)
ERTUGLIFLOZIN + SITAGLIPTIN, ertugliflozin 15 mg + sitagliptin 100 mg tablet, 28 (Steglujan 15/100)
ERTUGLIFLOZIN + SITAGLIPTIN, ertugliflozin 15 mg + sitagliptin 100 mg tablet, 28 (Steglujan 15/100)
ERTUGLIFLOZIN + SITAGLIPTIN, ertugliflozin 15 mg + sitagliptin 100 mg tablet, 28 (Steglujan 15/100)
GOLIMUMAB, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (Simponi)
GOLIMUMAB, golimumab 50 mg/0.5 mL injection, 0.5 mL injection device (Simponi)
GOLIMUMAB, golimumab 50 mg/0.5 mL injection, 0.5 mL injection device (Simponi)
GOLIMUMAB, golimumab 50 mg/0.5 mL injection, 0.5 mL syringe (Simponi)
GOLIMUMAB, golimumab 100 mg/mL injection, 1 mL injection device (Simponi)
GOLIMUMAB, golimumab 50 mg/0.5 mL injection, 0.5 mL injection device (Simponi)
GOLIMUMAB, golimumab 50 mg/0.5 mL injection, 0.5 mL injection device (Simponi)
METHOTREXATE, methotrexate 7.5 mg/0.3 mL injection, 4 x 0.3 mL syringes (Methoblastin PFS)
METHOTREXATE, methotrexate 10 mg/0.4 mL injection, 4 x 0.4 mL syringes (Methoblastin PFS)
METHOTREXATE, methotrexate 15 mg/0.6 mL injection, 4 x 0.6 mL syringes (Methoblastin PFS)
METHOTREXATE, methotrexate 20 mg/0.8 mL injection, 4 x 1 mL syringes (Methoblastin PFS)
METHOTREXATE, methotrexate 25 mg/mL injection, 4 x 1 mL syringes (Methoblastin PFS)
OLAPARIB, olaparib 100 mg tablet, 2 x 56 (Lynparza)
OLAPARIB, olaparib 100 mg tablet, 2 x 56 (Lynparza)
OLAPARIB, olaparib 150 mg tablet, 2 x 56 (Lynparza)
OLAPARIB, olaparib 150 mg tablet, 2 x 56 (Lynparza)
SITAGLIPTIN, sitagliptin 25 mg tablet, 28 (Januvia)
SITAGLIPTIN, sitagliptin 50 mg tablet, 28 (Januvia)
SITAGLIPTIN, sitagliptin 100 mg tablet, 28 (Januvia)
SITAGLIPTIN + METFORMIN, sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56 (Janumet)
SITAGLIPTIN + METFORMIN, sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56 (Janumet)
SITAGLIPTIN + METFORMIN, sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56 (Janumet)
SITAGLIPTIN + METFORMIN, sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56 (Janumet XR)
SITAGLIPTIN + METFORMIN, sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28 (Janumet XR)
Tocilizumab, tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL injection devices (Actemra ACTPen)
Tocilizumab, tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL injection devices (Actemra ACTPen)
TRIFLURIDINE + TIPIRACIL, trifluridine 15 mg + tipiracil 6.14 mg tablet, 20 (Lonsurf 15/6.14)
TRIFLURIDINE + TIPIRACIL, trifluridine 20 mg + tipiracil 8.19 mg tablet, 20 (Lonsurf 20/8.19)
Addition – Brand
Flucloxacillin GH, GQ – FLUCLOXACILLIN, flucloxacillin 500 mg capsule, 24
Flucloxacillin GH, GQ – FLUCLOXACILLIN, flucloxacillin 500 mg capsule, 24
Flucloxacillin GH, GQ – FLUCLOXACILLIN, flucloxacillin 500 mg capsule, 24
S-26 Original Alula L.I., AS – MILK POWDER LACTOSE INTOLERANCE FORMULA, milk powder lactose intolerance formula powder for oral liquid, 900 g
2606E Rosuvastatin APOTEX, GX – ROSUVASTATIN, rosuvastatin 5 mg tablet, 30
2584B BTC Rosuvastatin, JB – ROSUVASTATIN, rosuvastatin 10 mg tablet, 30
2584B Rosuvastatin APOTEX, GX – ROSUVASTATIN, rosuvastatin 10 mg tablet, 30
2628H BTC Rosuvastatin, JB – ROSUVASTATIN, rosuvastatin 10 mg tablet, 30
2628H Rosuvastatin APOTEX, GX – ROSUVASTATIN, rosuvastatin 10 mg tablet, 30
2574L BTC Rosuvastatin, JB – ROSUVASTATIN, rosuvastatin 20 mg tablet, 30
2574L Rosuvastatin APOTEX, GX – ROSUVASTATIN, rosuvastatin 20 mg tablet, 30
2609H BTC Rosuvastatin, JB – ROSUVASTATIN, rosuvastatin 20 mg tablet, 30
2609H Rosuvastatin APOTEX, GX – ROSUVASTATIN, rosuvastatin 20 mg tablet, 30
2574L BTC Rosuvastatin, JB – ROSUVASTATIN, rosuvastatin 40 mg tablet, 30
2574L Rosuvastatin APOTEX, GX – ROSUVASTATIN, rosuvastatin 40 mg tablet, 30
2636R BTC Rosuvastatin, JB – ROSUVASTATIN, rosuvastatin 40 mg tablet, 30
2636R Rosuvastatin APOTEX, GX – ROSUVASTATIN, rosuvastatin 40 mg tablet, 30

Addition – Equivalence Indicator
11275K Trejject, LM – METHOTREXATE, methotrexate 7.5 mg/0.15 mL injection, 0.15 mL syringe
11283W Trejject, LM – METHOTREXATE, methotrexate 10 mg/0.2 mL injection, 0.2 mL syringe
11268C Trejject, LM – METHOTREXATE, methotrexate 15 mg/0.3 mL injection, 0.3 mL syringe
11288D Trejject, LM – METHOTREXATE, methotrexate 20 mg/0.4 mL injection, 0.4 mL syringe
11295L Trejject, LM – METHOTREXATE, methotrexate 25 mg/0.5 mL injection, 0.5 mL syringe

Addition – Note
1805B CLONAZEPAM, clonazepam 500 microgram tablet, 100 (Paxam 0.5, Rivotril)
11275K METHOTREXATE, methotrexate 7.5 mg/0.15 mL injection, 0.15 mL syringe (Trejject)
11283W METHOTREXATE, methotrexate 10 mg/0.2 mL injection, 0.2 mL syringe (Trejject)
11268C METHOTREXATE, methotrexate 15 mg/0.3 mL injection, 0.3 mL syringe (Trejject)
11288D METHOTREXATE, methotrexate 20 mg/0.4 mL injection, 0.4 mL syringe (Trejject)
11295L METHOTREXATE, methotrexate 25 mg/0.5 mL injection, 0.5 mL syringe (Trejject)

Addition – Restriction
9180E SITAGLIPTIN, sitagliptin 25 mg tablet, 28 (Januvia)
9181F SITAGLIPTIN, sitagliptin 50 mg tablet, 28 (Januvia)
9182G SITAGLIPTIN, sitagliptin 100 mg tablet, 28 (Januvia)
9449H SITAGLIPTIN + METFORMIN, sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56 (Janumet)
9450J SITAGLIPTIN + METFORMIN, sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56 (Janumet)
10090C SITAGLIPTIN + METFORMIN, sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56 (Janumet XR)
9451K SITAGLIPTIN + METFORMIN, sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56 (Janumet)
10089B SITAGLIPTIN + METFORMIN, sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28 (Janumet XR)

Deletions
Deletion – Item
10013B BENZATROPINE, benztropine mesilate 2 mg/2 mL injection, 10 x 2 mL vials (Benztropine Omega)
10027R BENZATROPINE, benztropine mesilate 2 mg/2 mL injection, 10 x 2 mL vials (Benztropine Omega)

Deletion – Brand
11209Y S-26 Original LI, AS – MILK POWDER LACTOSE INTOLERANCE FORMULA, milk powder lactose intolerance formula powder for oral liquid, 900 g
8378Y  Temodal, MK – TEMOZOLOMIDE, temozolomide 5 mg capsule, 5
8819E  Temodal, MK – TEMOZOLOMIDE, temozolomide 5 mg capsule, 5
8379B  Temodal, MK – TEMOZOLOMIDE, temozolomide 20 mg capsule, 5
8820F  Temodal, MK – TEMOZOLOMIDE, temozolomide 20 mg capsule, 5

**Deletion – Note**

11382C  GOLUMUMAB, golimumab 100 mg/mL injection, 1 mL injection device *(Simponi)*

**Deletion – Restriction**

11382C  GOLUMUMAB, golimumab 100 mg/mL injection, 1 mL injection device *(Simponi)*

**Alterations**

**Alteration – Item Description**

<table>
<thead>
<tr>
<th>From</th>
<th>To</th>
</tr>
</thead>
<tbody>
<tr>
<td>8959M</td>
<td>DALTEPARIN SODIUM, DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 15,000 units (anti-Xa) in 0.6 mL single dose pre-filled syringe, 10 <em>(Fragmin)</em></td>
</tr>
<tr>
<td>To</td>
<td>DALTEPARIN SODIUM, dalteparin sodium 15 000 anti-Xa units/0.6 mL injection, 10 x 0.6 mL syringes <em>(Fragmin)</em></td>
</tr>
<tr>
<td>8960N</td>
<td>DALTEPARIN SODIUM, DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 18,000 units (anti-Xa) in 0.72 mL single dose pre-filled syringe, 10 <em>(Fragmin)</em></td>
</tr>
<tr>
<td>To</td>
<td>DALTEPARIN SODIUM, dalteparin sodium 18 000 anti-Xa units/0.72 mL injection, 10 x 0.72 mL syringes <em>(Fragmin)</em></td>
</tr>
<tr>
<td>1288T</td>
<td>DEXAMETHASONE, DEXAMETHASONE Eye drops 1 mg per mL (0.1%), 5 mL, 1 <em>(Maxidex)</em></td>
</tr>
<tr>
<td>To</td>
<td>DEXAMETHASONE, dexamethasone 0.1% eye drops, 5 mL <em>(Maxidex)</em></td>
</tr>
<tr>
<td>5565X</td>
<td>DEXAMETHASONE, DEXAMETHASONE Eye drops 1 mg per mL (0.1%), 5 mL, 1 <em>(Maxidex)</em></td>
</tr>
<tr>
<td>To</td>
<td>DEXAMETHASONE, dexamethasone 0.1% eye drops, 5 mL <em>(Maxidex)</em></td>
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<tr>
<td>1292B</td>
<td>DEXAMETHASONE, DEXAMETHASONE Tablet 500 micrograms, 30 <em>(Dexmethsone)</em></td>
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<td>DEXAMETHASONE, dexamethasone 500 microgram tablet, 30 <em>(Dexmethsone)</em></td>
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<tr>
<td>2507Y</td>
<td>DEXAMETHASONE, DEXAMETHASONE Tablet 4 mg, 30 <em>(Dexmethsone)</em></td>
</tr>
<tr>
<td>To</td>
<td>DEXAMETHASONE, dexamethasone 4 mg tablet, 30 <em>(Dexmethsone)</em></td>
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<tr>
<td>1291Y</td>
<td>DEXAMETHASONE PHOSPHATE, DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 8 mg dexamethasone phosphate in 2 mL, 5 <em>(Dexamethasone Mylan, Hospira Pty Limited)</em></td>
</tr>
<tr>
<td>To</td>
<td>DEXAMETHASONE PHOSPHATE, dexamethasone phosphate 8 mg/2 mL injection, 5 x 2 mL vials <em>(Dexamethasone Mylan, Hospira Pty Limited)</em></td>
</tr>
<tr>
<td>8671J</td>
<td>IPRATROPIUM, ipratropium bromide 20 microgram/actuation inhalation: pressurised, 200 actuations <em>(Atrovent)</em></td>
</tr>
<tr>
<td>To</td>
<td>IPRATROPIUM, ipratropium bromide monohydrate 21 microgram/actuation pressurised inhalation, 200 actuations <em>(Atrovent)</em></td>
</tr>
<tr>
<td>8218M</td>
<td>LEVODOPA + BENSERAZIDE, LEVODOPA with BENSERAZIDE Dispersible tablet 50 mg-12.5 mg, 100 <em>(Madopar Rapid 62.5)</em></td>
</tr>
<tr>
<td>To</td>
<td>LEVODOPA + BENSERAZIDE, levodopa 50 mg + benserazide 12.5 mg dispersible tablet, 100 <em>(Madopar Rapid 62.5)</em></td>
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<tr>
<td>8219N</td>
<td>LEVODOPA + BENSERAZIDE, LEVODOPA with BENSERAZIDE Dispersible tablet 100 mg-25 mg, 100 <em>(Madopar Rapid 125)</em></td>
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<tr>
<td>To</td>
<td>LEVODOPA + BENSERAZIDE, levodopa 100 mg + benserazide 25 mg dispersible tablet, 100 <em>(Madopar Rapid 125)</em></td>
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<td>From</td>
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<tr>
<td>5263B</td>
<td>METHYLPREDNISOLONE, methylprednisolone Powder for injection 40 mg (as sodium succinate), 5 (Methylpred)</td>
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<tr>
<td>5263B</td>
<td>METHYLPREDNISOLONE, methylprednisolone 40 mg injection, 5 vials (Methylpred)</td>
</tr>
<tr>
<td>5264C</td>
<td>METHYLPREDNISOLONE, methylprednisolone Powder for injection 1 g (as sodium succinate), 1 (Methylpred, Methylprednisolone Alphapharm, Solu-Medrol)</td>
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<tr>
<td>5264C</td>
<td>METHYLPREDNISOLONE, methylprednisolone 1 g injection, 1 vial (Methylpred, Methylprednisolone Alphapharm, Solu-Medrol)</td>
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<tr>
<td>1309X</td>
<td>NILOTINIB, NILOTINIB Capsule 150 mg (as hydrochloride monohydrate), 120 (Tasigna)</td>
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<tr>
<td>1309X</td>
<td>NILOTINIB, nilotinib 150 mg capsule, 120 (Tasigna)</td>
</tr>
<tr>
<td>9171Q</td>
<td>NILOTINIB, NILOTINIB Capsule 200 mg (as hydrochloride monohydrate), 120 (Tasigna)</td>
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<tr>
<td>9171Q</td>
<td>NILOTINIB, nilotinib 200 mg capsule, 120 (Tasigna)</td>
</tr>
<tr>
<td>1952R</td>
<td>RASAGILINE, RASAGILINE Tablet 1 mg (as mesilate), 30 (Azilect)</td>
</tr>
<tr>
<td>1952R</td>
<td>RASAGILINE, rasagiline 1 mg tablet, 30 (Azilect)</td>
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<tr>
<td>8972F</td>
<td>RISEDRONATE, RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4 (Actonel EC)</td>
</tr>
<tr>
<td>8972F</td>
<td>RISEDRONATE, risedronate sodium 35 mg enteric tablet, 4 (Actonel EC)</td>
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</table>

**Alteration – Note**

| 9033K        | ADALIMUMAB, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (Humira) |
| 9034L        | ADALIMUMAB, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (Humira) |
| 9101B        | ADALIMUMAB, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (Humira) |
| 9102C        | ADALIMUMAB, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (Humira) |
| 10238W       | CERTOLIZUMAB PEGOL, certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (Cimzia) |
| 10896L       | CERTOLIZUMAB PEGOL, certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (Cimzia) |
| 10909E       | CERTOLIZUMAB PEGOL, certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (Cimzia) |
| 11323Y       | CERTOLIZUMAB PEGOL, certolizumab pegol 200 mg/mL injection, 2 x 1 mL injection devices (Cimzia) |
| 11324B       | CERTOLIZUMAB PEGOL, certolizumab pegol 200 mg/mL injection, 2 x 1 mL injection devices (Cimzia) |
| 11326D       | CERTOLIZUMAB PEGOL, certolizumab pegol 200 mg/mL injection, 2 x 1 mL injection devices (Cimzia) |
| 11207W       | ETANERCEPT, etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (Enbrel) |
| 9035M        | ETANERCEPT, etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (Enbrel) |
| 9036N        | ETANERCEPT, etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (Enbrel) |
| 11198J       | ETANERCEPT, etanercept 50 mg/mL injection, 4 x 1 mL injection devices (Enbrel) |
| 11202N       | ETANERCEPT, etanercept 50 mg/mL injection, 4 x 1 mL injection devices (Brenzys) |
| 9457R        | ETANERCEPT, etanercept 50 mg/mL injection, 4 x 1 mL injection devices (Brenzys, Enbrel) |
| 9458T        | ETANERCEPT, etanercept 50 mg/mL injection, 4 x 1 mL injection devices (Brenzys, Enbrel) |
| 11208X       | ETANERCEPT, etanercept 50 mg/mL injection, 4 x 1 mL syringes (Enbrel) |
| 11216H       | ETANERCEPT, etanercept 50 mg/mL injection, 4 x 1 mL syringes (Brenzys) |
| 9087G        | ETANERCEPT, etanercept 50 mg/mL injection, 4 x 1 mL syringes (Brenzys, Enbrel) |
| 9088H        | ETANERCEPT, etanercept 50 mg/mL injection, 4 x 1 mL syringes (Brenzys, Enbrel) |
| 11365E       | GOLIMUMAB, golimumab 50 mg/0.5 mL injection, 0.5 mL injection device (Simpsoni) |
| 11373N       | GOLIMUMAB, golimumab 50 mg/0.5 mL injection, 0.5 mL injection device (Simpsoni) |
| 10894J       | SECUKINUMAB, secukinumab 150 mg/mL injection, 2 x 1 mL injection devices (Cosentyx) |
10895K SECUKINUMAB, secukinumab 150 mg/mL injection, 1 mL injection device (Cosentyx)
10898N SECUKINUMAB, secukinumab 150 mg/mL injection, 1 mL injection device (Cosentyx)
10899P SECUKINUMAB, secukinumab 150 mg/mL injection, 2 x 1 mL injection devices (Cosentyx)
10900Q SECUKINUMAB, secukinumab 150 mg/mL injection, 1 mL injection device (Cosentyx)
10901R SECUKINUMAB, secukinumab 150 mg/mL injection, 2 x 1 mL injection devices (Cosentyx)
9180E SITAGLIPTIN, sitagliptin 25 mg tablet, 28 (Januvia)
9181F SITAGLIPTIN, sitagliptin 50 mg tablet, 28 (Januvia)
9182G SITAGLIPTIN, sitagliptin 100 mg tablet, 28 (Januvia)
9449H SITAGLIPTIN + METFORMIN, sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56 (Janumet)
9450J SITAGLIPTIN + METFORMIN, sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56 (Janumet)
10090C SITAGLIPTIN + METFORMIN, sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56 (Janumet XR)
10089B SITAGLIPTIN + METFORMIN, sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56 (Janumet)
10951J TOCILIZUMAB, tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (Actemra Subcutaneous Injection)
10954M TOCILIZUMAB, tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (Actemra Subcutaneous Injection)
10767Q USTEKINUMAB, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial (Stelara)
10774C USTEKINUMAB, ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial (Stelara)

**Alteration – Restriction**
10895K SECUKINUMAB, secukinumab 150 mg/mL injection, 1 mL injection device (Cosentyx)
10899P SECUKINUMAB, secukinumab 150 mg/mL injection, 2 x 1 mL injection devices (Cosentyx)
10951J TOCILIZUMAB, tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (Actemra Subcutaneous Injection)
10954M TOCILIZUMAB, tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes (Actemra Subcutaneous Injection)

**Alteration – Manufacturer Code**

<table>
<thead>
<tr>
<th>From</th>
<th>To</th>
</tr>
</thead>
<tbody>
<tr>
<td>1214X Aspen Pharma Pty Ltd – CODEINE</td>
<td>FM QA</td>
</tr>
<tr>
<td>5063L Aspen Pharma Pty Ltd – CODEINE</td>
<td>FM QA</td>
</tr>
</tbody>
</table>

**Alteration – Maximum Quantity**
11382C GOLIMUMAB, golimumab 100 mg/mL injection, 1 mL injection device (Simponi) From 1 To 3

**Alteration – Number of Repeats**
11382C GOLIMUMAB, golimumab 100 mg/mL injection, 1 mL injection device (Simponi) From 4 To 0

**Advance Notices**

**1 January 2019**

**Deletion – Brand**
1695F Adalat 20, BN – NIFEDIPINE, nifedipine 20 mg tablet, 60
8622T Pritor Plus 40/12.5 mg, FI – TELMISARTAN + HYDROCHLOROTHIAZIDE, telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28
8623W Pritor Plus 80/12.5 mg, FI – TELMISARTAN + HYDROCHLOROTHIAZIDE, telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28
9381R Pritor Plus 80/25 mg, FI – TELMISARTAN + HYDROCHLOROTHIAZIDE, telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28
1 February 2019

Deletion – Brand

8726G Copaxone, TB – GLATIRAMER ACETATE, glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes
8010N Nitro-Dur 5, MK – GLYCERYL TRINITRATE, glyceryl trinitrate 5 mg/24 hours patch, 30
8011P Nitro-Dur 10, MK – GLYCERYL TRINITRATE, glyceryl trinitrate 10 mg/24 hours patch, 30
8026K Nitro-Dur 15, MK – GLYCERYL TRINITRATE, glyceryl trinitrate 15 mg/24 hours patch, 30
10359F PKU Glytactin RTD 10, QH – GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS, glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g of protein equivalent oral liquid, 30 x 250 mL cartons
2696X Camino Pro Complete, QH – GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS, glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 54 g
2448W Zavedos, PF – IDARUBICIN, idarubicin hydrochloride 10 mg capsule, 1
1694E Adalat 10, BN – NIFEDIPINE, nifedipine 10 mg tablet, 60
10766P Viekira Pak, VE – PARITAPREVI R + RITONAVIR + OMBITASVIR & DASABUVIR, paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56], 4 x 28
10747P Viekira Pak-RBV, VE – PARITAPREVI R + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN, paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack
10769T Viekira Pak-RBV, VE – PARITAPREVI R + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN, paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack
10771X Viekira Pak-RBV, VE – PARITAPREVI R + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN, paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack
10772Y Viekira Pak-RBV, VE – PARITAPREVI R + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN, paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack
8444K Gelofusine, BR – SUCCINYLATED GELATIN, succinylated gelatin 20 g/500 mL injection, 500 mL bag

1 March 2019

Deletion – Brand

1002R Zovirax, GK – ACICLOVIR, aciclovir 3% eye ointment, 4.5 g
5501M Zovirax, GK – ACICLOVIR, aciclovir 3% eye ointment, 4.5 g
2738D XP Maxamaid, SB – AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE, amino acid formula with vitamins and minerals without phenylalanine powder for oral liquid, 500 g

1 April 2019

Deletion – Brand

8362D Xeloda, RO – CAPECITABINE, capecitabine 500 mg tablet, 120
5132D Dilaudid, MF – HYDROMORPHONE, hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL
8424J Dilaudid, MF – HYDROMORPHONE, hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL

1 September 2019

Deletion – Brand

1711C Hypurin Isophane, AS – INSULIN ISOPHANE BOVINE, insulin isophane bovine 100 units/mL injection, 1 x 10 mL vial
1713E Hypurin Neutral, AS – INSULIN NEUTRAL BOVINE, insulin neutral bovine 100 units/mL injection, 1 x 10 mL vial

Palliative Care

Additions

Addition – Item

11520H CLONAZEPAM, clonazepam 500 microgram tablet, 50 (Rivotril)
**Addition – Note**

5337X \textbf{CLONAZEPAM}, clonazepam 500 microgram tablet, 100 (Paxam 0.5, Rivotril)

**Alterations**

**Alteration – Item Description**

<table>
<thead>
<tr>
<th>From</th>
<th>To</th>
</tr>
</thead>
<tbody>
<tr>
<td>5424L</td>
<td>METHYLNALTREXONE, METHYLNALTREXONE Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL, 7 (Relistor)</td>
</tr>
<tr>
<td>5424L</td>
<td>METHYLNALTREXONE, methylnaltrexone bromide 12 mg/0.6 mL injection, 7 x 0.6 mL vials (Relistor)</td>
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</tbody>
</table>

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

**Additions**

**Addition – Item**

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11504L</td>
<td>BENRALIZUMAB, benralizumab 30 mg/mL injection, 1 mL syringe (Fasenra)</td>
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<tr>
<td>11523L</td>
<td>BENRALIZUMAB, benralizumab 30 mg/mL injection, 1 mL syringe (Fasenra)</td>
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<tr>
<td>11545P</td>
<td>DEFERASIROX, deferasirox 90 mg tablet, 30 (Jadenu)</td>
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<tr>
<td>11548T</td>
<td>DEFERASIROX, deferasirox 90 mg tablet, 30 (Jadenu)</td>
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<tr>
<td>11558H</td>
<td>DEFERASIROX, deferasirox 90 mg tablet, 30 (Jadenu)</td>
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<td>11510T</td>
<td>DEFERASIROX, deferasirox 180 mg tablet, 30 (Jadenu)</td>
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<td>11546Q</td>
<td>DEFERASIROX, deferasirox 180 mg tablet, 30 (Jadenu)</td>
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<td>11557G</td>
<td>DEFERASIROX, deferasirox 180 mg tablet, 30 (Jadenu)</td>
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<td>11496C</td>
<td>DEFERASIROX, deferasirox 360 mg tablet, 30 (Jadenu)</td>
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<td>11511W</td>
<td>DEFERASIROX, deferasirox 360 mg tablet, 30 (Jadenu)</td>
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<td>DEFERASIROX, deferasirox 360 mg tablet, 30 (Jadenu)</td>
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<td>11498E</td>
<td>INFLIXIMAB, infliximab 100 mg injection, 1 vial (Remicade)</td>
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<tr>
<td>11515C</td>
<td>INFLIXIMAB, infliximab 100 mg injection, 1 vial (Inflectra, Renflexis)</td>
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<tr>
<td>11527Q</td>
<td>LANREOTIDE, lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe (Somatuline Autogel)</td>
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<td>11517E</td>
<td>LENOGRASTIM, lenograstim 13.4 million units (105 microgram) injection, 1 vial (Granocyte 13)</td>
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<tr>
<td>11530W</td>
<td>LENOGRASTIM, lenograstim 33.6 million units (263 microgram) injection, 1 vial (Granocyte 34)</td>
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<tr>
<td>11506N</td>
<td>MIDOSTAURIN, midostaurin 25 mg capsule, 56 (Rydapt)</td>
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<tr>
<td>11518F</td>
<td>MIDOSTAURIN, midostaurin 25 mg capsule, 112 (Rydapt)</td>
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<tr>
<td>11531X</td>
<td>MIDOSTAURIN, midostaurin 25 mg capsule, 112 (Rydapt)</td>
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<tr>
<td>11541K</td>
<td>MIDOSTAURIN, midostaurin 25 mg capsule, 112 (Rydapt)</td>
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**Addition – Note**

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11236J</td>
<td>DEFERASIROX, deferasirox 125 mg dispersible tablet, 28 (Exjade)</td>
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<tr>
<td>11241P</td>
<td>DEFERASIROX, deferasirox 125 mg dispersible tablet, 28 (Exjade)</td>
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<td>6499C</td>
<td>DEFERASIROX, deferasirox 125 mg dispersible tablet, 28 (Exjade)</td>
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<td>11238L</td>
<td>DEFERASIROX, deferasirox 250 mg dispersible tablet, 28 (Exjade)</td>
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<td>11244T</td>
<td>DEFERASIROX, deferasirox 250 mg dispersible tablet, 28 (Exjade)</td>
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<td>6500D</td>
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<td>DEFERASIROX, deferasirox 500 mg dispersible tablet, 28 (Exjade)</td>
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<td>11243R</td>
<td>DEFERASIROX, deferasirox 500 mg dispersible tablet, 28 (Exjade)</td>
</tr>
<tr>
<td>9600G</td>
<td>DEFERASIROX, deferasirox 500 mg dispersible tablet, 28 (Exjade)</td>
</tr>
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</table>
Deletions
Deletion – Item
6337M LENOGRASTIM, LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10 (Granocyte 13)
6338N LENOGRASTIM, LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10 (Granocyte 34)

Alterations
Alteration – Item Description
From 2008Q MANNITOL, MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1 (bronchitol)
To 2008Q MANNITOL, mannitol 40 mg powder for inhalation, 280 capsules (bronchitol)

Alteration – Note
6496X INFLIXIMAB, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Renflexis)
11003D MEPOLIZUMAB, mepolizumab 100 mg injection, 1 vial (Nucala)
11014Q MEPOLIZUMAB, mepolizumab 100 mg injection, 1 vial (Nucala)
10110D OMALIZUMAB, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe (Xolair)
10122R OMALIZUMAB, omalizumab 150 mg/mL injection, 1 mL syringe (Xolair)

Alteration – Restriction
5830W FILGRASTIM, filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes (Nivestim)
2747N FILGRASTIM, filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes (Zarzio)
9693E FILGRASTIM, filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes (Nivestim)
2733W FILGRASTIM, filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes (Zarzio)
9695G FILGRASTIM, filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes (Nivestim)
6496X INFLIXIMAB, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Renflexis)
11003D MEPOLIZUMAB, mepolizumab 100 mg injection, 1 vial (Nucala)
11014Q MEPOLIZUMAB, mepolizumab 100 mg injection, 1 vial (Nucala)
6227R OCTREOTIDE, octreotide 50 microgram/mL injection, 5 x 1 mL ampoules (Hospira Pty Limited, Octreotide (SUN), Octreotide MaxRx, Sandostatin 0.05)
6228T OCTREOTIDE, octreotide 100 microgram/mL injection, 5 x 1 mL ampoules (Hospira Pty Limited, Octreotide (SUN), Octreotide MaxRx, Sandostatin 0.1)
6229W OCTREOTIDE, octreotide 500 microgram/mL injection, 5 x 1 mL ampoules (Hospira Pty Limited, Octreotide (SUN), Octreotide MaxRx, Sandostatin 0.5)
10566D OCTREOTIDE, octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (Sandostatin LAR)
10549F OCTREOTIDE, octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (Sandostatin LAR)
10558Q OCTREOTIDE, octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (Sandostatin LAR)
10110D OMALIZUMAB, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe (Xolair)
10122R OMALIZUMAB, omalizumab 150 mg/mL injection, 1 mL syringe (Xolair)

Advance Notices
1 February 2019
Deletion – Brand
10749R Viekira Pak, VE – PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR, paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56], 4 x 28
Highly Specialised Drugs Program (Public Hospital)

Additions

**Addition – Item**

- **11529T** BENRALIZUMAB, benralizumab 30 mg/mL injection, 1 mL syringe (Fasenra)
- **11549W** BENRALIZUMAB, benralizumab 30 mg/mL injection, 1 mL syringe (Fasenra)
- **11499F** DEFERASIROX, deferasirox 90 mg tablet, 30 (Jadenu)
- **11519G** DEFERASIROX, deferasirox 90 mg tablet, 30 (Jadenu)
- **11534C** DEFERASIROX, deferasirox 90 mg tablet, 30 (Jadenu)
- **11500G** DEFERASIROX, deferasirox 180 mg tablet, 30 (Jadenu)
- **11535D** DEFERASIROX, deferasirox 180 mg tablet, 30 (Jadenu)
- **11536F** DEFERASIROX, deferasirox 180 mg tablet, 30 (Jadenu)
- **11533B** DEFERASIROX, deferasirox 360 mg tablet, 30 (Jadenu)
- **11536E** DEFERASIROX, deferasirox 360 mg tablet, 30 (Jadenu)
- **11555E** DEFERASIROX, deferasirox 360 mg tablet, 30 (Jadenu)
- **11497D** INFliximab, infliximab 100 mg injection, 1 vial (Remicade)
- **11514B** INFliximab, infliximab 100 mg injection, 1 vial (Inflectra, Renflexis)
- **11513Y** LANREOTIDE, lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe (Somatuline Autogel)
- **11505X** LENOGRASTIM, lenograstim 13.4 million units (105 microgram) injection, 1 vial (Granocyte 13)
- **11551Y** LENOGRASTIM, lenograstim 33.6 million units (263 microgram) injection, 1 vial (Granocyte 34)
- **11505M** MIDOSTAURIN, midostaurin 25 mg capsule, 112 (Rydapt)
- **11542L** MIDOSTAURIN, midostaurin 25 mg capsule, 112 (Rydapt)
- **11552B** MIDOSTAURIN, midostaurin 25 mg capsule, 112 (Rydapt)
- **11553C** MIDOSTAURIN, midostaurin 25 mg capsule, 56 (Rydapt)

**Addition – Note**

- **11235H** DEFERASIROX, deferasirox 125 mg dispersible tablet, 28 (Exjade)
- **11247Y** DEFERASIROX, deferasirox 125 mg dispersible tablet, 28 (Exjade)
- **5654N** DEFERASIROX, deferasirox 125 mg dispersible tablet, 28 (Exjade)
- **11239M** DEFERASIROX, deferasirox 250 mg dispersible tablet, 28 (Exjade)
- **11240N** DEFERASIROX, deferasirox 250 mg dispersible tablet, 28 (Exjade)
- **5655P** DEFERASIROX, deferasirox 250 mg dispersible tablet, 28 (Exjade)
- **11231D** DEFERASIROX, deferasirox 500 mg dispersible tablet, 28 (Exjade)
- **11234G** DEFERASIROX, deferasirox 500 mg dispersible tablet, 28 (Exjade)
- **5656Q** DEFERASIROX, deferasirox 500 mg dispersible tablet, 28 (Exjade)
Deletions

Deletion – Item

5787N LENOGRASTIM, LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10 (Granocyte 13)

5788P LENOGRASTIM, LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10 (Granocyte 34)

Alterations

Alteration – Item Description

From
2015C MANNITOL, MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1 (bronchitol)

To
2015C MANNITOL, mannitol 40 mg powder for inhalation, 280 capsules (bronchitol)

Alteration – Note

5756Y INFliximab, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Renflexis)

10980X MEPOLIZUMAB, mepolizumab 100 mg injection, 1 vial (Nucala)

10996R MEPOLIZUMAB, mepolizumab 100 mg injection, 1 vial (Nucala)

10118M OMALIZUMAB, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe (Xolair)

10109C OMALIZUMAB, omalizumab 150 mg/mL injection, 1 mL syringe (Xolair)

Alteration – Restriction

5829T FILGRASTIM, filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes (Nivestim)

2758E FILGRASTIM, filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes (Zarzio)

9692D FILGRASTIM, filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes (Nivestim)

2783L FILGRASTIM, filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes (Zarzio)

9694F FILGRASTIM, filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes (Nivestim)

5756Y INFliximab, infliximab 100 mg injection, 1 vial (Inflectra, Remicade, Renflexis)

10980X MEPOLIZUMAB, mepolizumab 100 mg injection, 1 vial (Nucala)

10996R MEPOLIZUMAB, mepolizumab 100 mg injection, 1 vial (Nucala)

9508K OCTREOTIDE, octreotide 50 microgram/mL injection, 5 x 1 mL ampoules (Hospira Pty Limited, Octreotide (SUN), Octreotide MaxRx, Sandostatin 0.05)

9509L OCTREOTIDE, octreotide 100 microgram/mL injection, 5 x 1 mL ampoules (Hospira Pty Limited, Octreotide (SUN), Octreotide MaxRx, Sandostatin 0.1)

9510M OCTREOTIDE, octreotide 500 microgram/mL injection, 5 x 1 mL ampoules (Hospira Pty Limited, Octreotide (SUN), Octreotide MaxRx, Sandostatin 0.5)

10543X OCTREOTIDE, octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (Sandostatin LAR)

10533J OCTREOTIDE, octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (Sandostatin LAR)

10550G OCTREOTIDE, octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (Sandostatin LAR)

10118M OMALIZUMAB, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe (Xolair)

10109C OMALIZUMAB, omalizumab 150 mg/mL injection, 1 mL syringe (Xolair)

Advance Notices

1 February 2019

Deletion – Brand

10751W Viekira Pak, VE – PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR, paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56], 4 x 28
Highly Specialised Drugs Program (Community Access)

Additions

Addition – Item

11540J **Dolutegravir + Rilpivirine**, dolutegravir 50 mg + rilpivirine 25 mg tablet, 30 *(Juluca)*

11501H **Octreotide**, octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

11537F **Octreotide**, octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

11512X **Octreotide**, octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Sandostatin LAR)*

Addition – Brand

10357D **Abacavir/Lamivudine 600/300 Sun, Ra** – **Abacavir + Lamivudine**, abacavir 600 mg + lamivudine 300 mg tablet, 30

Growth Hormone Program

Additions

Addition – Item

11491T **Somatropin**, somatropin 12 mg injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack *(Genotropin)*

11493X **Somatropin, Somatropin (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1 *(Genotropin GoQuick)*

11495B **Somatropin, Somatropin (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1 *(Genotropin GoQuick)*

Advance Notices

1 January 2019

Deletion – Brand

10444Q ***Genotropin, PF – Somatropin, somatropin 12 mg injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack***

10499N ***Genotropin, PF – Somatropin, somatropin 12 mg injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack***

6312F ***Genotropin, PF – Somatropin, somatropin 12 mg injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack***

Repatriation Pharmaceutical Benefits

Additions

Addition – Brand

4115N **Zithro, RF – Azithromycin**, azithromycin 500 mg tablet, 3
4321K  *Amcal Mag-A, IG – MAGNESIUM ASPARTATE DIHYDRATE*, magnesium aspartate dihydrate 500 mg (magnesium 37.4 mg) tablet, 50

4321K  *Pharmacy Care Magnesium, SI – MAGNESIUM ASPARTATE DIHYDRATE*, magnesium aspartate dihydrate 500 mg (magnesium 37.4 mg) tablet, 50

4522B  *Imoclone, RW – ZOPICLONE*, zopiclone 7.5 mg tablet, 30

**Deletions**

*Deletion – Item*

4551M  **DIMETICONE-350 + GLYCEROL**, dimeticone-350 15% + glycerol 2% cream, 500 g (*Silic 15*)

4556T  **DIMETICONE-350 + GLYCEROL**, dimeticone-350 15% + glycerol 2% cream, 75 g (*Silic 15*)

*Deletion – Brand*

4233T  *Finasteride Alphapharm, AF – FINASTERIDE*, finasteride 5 mg tablet, 30

4071G  *Duro-Tuss, IL – PHOLCODINE*, pholcodine 1 mg/mL oral liquid, 100 mL

**Alterations**

*Alteration – Item Description*

*From*

4281H  **ICHTHAMMOL**, ichthammol Cream 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g, 1 (*Egoderm Cream*)

*To*

4281H  **ICHTHAMMOL**, ichthammol 1% cream, 50 g (*Egoderm Cream*)

*From*

2191H  **RISEDRONATE**, RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4 (*Actonel EC*)

*To*

2191H  **RISEDRONATE**, risedronate sodium 35 mg enteric tablet, 4 (*Actonel EC*)
General Pharmaceutical Benefits

### 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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,

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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.

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 recommencement of treatment after more than 5 years break in therapy); or

   (ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

   (iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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

   (iv) a patient wishes to re-commence 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 therapy 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 and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

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.

   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.

   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.
For second and subsequent continuing 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.

(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.

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 a 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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note** No 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

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 - balance of supply**

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Adalimumab

#### Adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>39.50 Humira [VE]</td>
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#### Adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

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<tr>
<th>Max.Qty Packs</th>
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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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy,

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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.
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 recommencement of treatment after more than 5 years break in therapy); or
(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy): or
(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Re-commencement of treatment after a break in therapy 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 and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

(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.

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.

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.

For second and subsequent continuing 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.

(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.

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 a 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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or lefunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note: No 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 or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:
- Patient must have severe active psoriatic arthritis, AND
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- An elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
- Either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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)

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, AND
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment. **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**
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
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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the same cycle.

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.

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.

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.

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 recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Re-commencement of treatment after a break in therapy of less than 5 years).

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
sodium, sodium carbonate, sodium metabisulfite, and purified water. Each mL of Cimzia [UC] contains 10 mg of certolizumab pegol.

**Clinical Studies**

**Phase II Study**

A total of 514 patients with moderate to severe active psoriatic arthritis (102 patients in the placebo group, 102 patients in the 40 mg dose group, and 110 patients in the 80 mg dose group) were randomly assigned to receive placebo, certolizumab pegol 40 mg subcutaneously at week 0, and then at weeks 4, 8, 12, and 16, or placebo, certolizumab pegol 80 mg subcutaneously at week 0, and then at weeks 4, 8, 12, and 16. The primary endpoint was the change from baseline minus 13 to the number of tender joints (28 Joints) at week 16.

**Phase III Study**

A total of 1016 patients with moderate to severe active psoriatic arthritis (254 patients in the placebo group, 254 patients in the certolizumab pegol 200 mg/mL dose group, and 254 patients in the certolizumab pegol 400 mg/mL dose group) were randomly assigned to receive placebo, certolizumab pegol 200 mg/mL subcutaneously at week 0, and then at weeks 4, 8, 12, 16, 20, and 24, or placebo, certolizumab pegol 400 mg/mL subcutaneously at week 0, and then at weeks 4, 8, 12, 16, 20, and 24. The primary endpoint was the change from baseline minus 13 to the number of tender joints (28 Joints) at week 24.

**Conclusion**

Certolizumab pegol was shown to be efficacious in the treatment of moderate to severe active psoriatic arthritis, with significant improvements in disease activity compared to placebo.

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**Notes**

- **Authority required**
  - Severe psoriatic arthritis
  - Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

- **Clinical criteria:**
  - Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 18 to 20 weeks treatment, OR
  - Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 18 to 20 weeks treatment, AND
  - The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

- **Treatment criteria:**
  - Must be treated by a rheumatologist; OR
  - Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

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**Cimzia [UC]**

- **Brand Name**: Cimzia [UC]
- **Manufacturer**: UCB

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**Colestipol**

- **Brand Name**: Colestipol
- **Manufacturer**: Merck

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**Colestipol Tablets**

- **Brand Name**: Colestipol Tablets
- **Manufacturer**: Merck

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**Colestipol Suspension**

- **Brand Name**: Colestipol Suspension
- **Manufacturer**: Merck

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**Colestipol Syrup**

- **Brand Name**: Colestipol Syrup
- **Manufacturer**: Merck
etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.

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 recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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

(iv) a patient wishes to re-commence 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 therapy 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 and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

(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.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. 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.

For second and subsequent continuing 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.

(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.

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 a 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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the
commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or lefunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note No increase 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

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
either of the following:

  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### Certolizumab pegol 200 mg/mL injection, 2 x 1 mL injection devices

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### Certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

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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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.

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 recommencement of treatment after more than 5 years break in therapy); or
     (ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or
     (iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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
     (iv) a patient wishes to re-commence 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 therapy 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 and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

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.

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.

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.

For second and subsequent continuing 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.

(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.

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 a 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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

Note Special Pricing Arrangements apply.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.
Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.
Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.
The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
either
(a) an active joint count of at least 20 active (swollen and tender) joints; or
(b) at least 4 active joints from the following list of major joints:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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)

**Clinical criteria:**
- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.
Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.
Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.
Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.
Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.
An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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

certolizumab pegol 200 mg/mL injection, 2 x 1 mL injection devices

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**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

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clonazepam 500 microgram tablet, 50

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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 glitazone 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

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) 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**

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing 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 with a gliptin; or
- an SGLT2 inhibitor with a glitazone.
ertugliflozin 15 mg tablet, 28
11571B

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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 with a gliptin; 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 7.5 mg + metformin hydrochloride 500 mg tablet, 56
11562M

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**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, an 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), 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 eruditiflozin.

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 a glitazone; or
- an SGLT2 inhibitor with a glitazone.

ertugliflozin 7.5 mg + metformin hydrochloride 500 mg tablet, 56

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ertugliflozin 2.5 mg + metformin hydrochloride 500 mg tablet, 56

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ertugliflozin 7.5 mg + metformin hydrochloride 1 g 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 of 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 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 glitazone, must be documented in the patient’s medical records.

**Ertugliflozin 15 mg + Sitagliptin 100 mg tablet, 28**

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**Ertugliflozin 5 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.

**Ertugliflozin 15 mg + Sitagliptin 100 mg tablet, 28**

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**Ertugliflozin 5 mg + Sitagliptin 100 mg tablet, 28**

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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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

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 \(5\) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.

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 recommencement of treatment after more than 5 years break in therapy); or
(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or
(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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
(iv) a patient wishes to re-commence 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 therapy 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 and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

(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.

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. 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. For second and subsequent continuing 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.

(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.

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 a 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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note No 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)**

7217

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **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 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.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

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 be documented in the patient's medical notes.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was issued in this cycle and the date of the first application under a new cycle.

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

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**etanercept 50 mg/mL injection, 4 x 1 mL injection 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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

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 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.

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 recommencement of treatment after more than 5 years break in therapy); or
   - (ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or
   - (iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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
   - (iv) a patient wishes to re-commence 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
therapy 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 and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

(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. 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. 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. For second and subsequent continuing 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.

(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. 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 a 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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note: No 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: Subsequent continuing treatment

**Clinical criteria:**
- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, AND
- Patient must have demonstrated an adequate response to treatment with this drug.

**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.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

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.

Each application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. Where a response assessment is not submitted the patient will be deemed to have failed to respond to treatment with this drug.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

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

Applications for authority to prescribe should be forwarded to:
Department of Human Services
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.

**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.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

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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 injection 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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. Where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.
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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle. 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.

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.

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.

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 recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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

(iv) a patient wishes to re-commence 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 therapy 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 and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

(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.

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. A patient may be assessed for response to every course of continuing treatment, 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.

For second and subsequent continuing 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.

(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.

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 a 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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note
No 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: First continuing treatment
Clinical criteria:
• Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND
• Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND
• Patient must not receive more than 24 weeks of treatment 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.
For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.
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 for all subsequent continuing treatments.

The application for first continuing treatment with this drug must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 - 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.
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.

**Note**
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

### etanercept 50 mg/mL injection, 4 x 1 mL syringes

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<tr>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>Brenzys [MK]</td>
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### etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

### etanercept 50 mg/mL injection, 4 x 1 mL injection 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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.

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 recommencement of treatment after more than 5 years break in therapy); or
(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or
(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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
(iv) a patient wishes to re-commence 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 therapy 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 and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

(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.

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. 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.

For second and subsequent continuing 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.

(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.

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 a 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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note No 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 or patient recommencing treatment after a break of 5 years or more)**

**Clinical criteria:**

- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be 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.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.
Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
- either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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).

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 of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**
- Patient must not 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.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received...
previous PBS-subsidised biological therapy with this biological agent), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was accessed under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted, where applicable to the Department of Human Services.

Where this is the initial course of treatment with a particular biological agent (change of treatment) 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.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was issued in this cycle and the date of the first application under a new cycle.

An adequate response to treatment is defined as:
an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment after a break of less 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 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.

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.

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

etanercept 50 mg/mL injection, 4 x 1 mL syringes
9087G

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

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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 adalimumab, golimumab, infliximab or vedolizumab 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 adalimumab, golimumab, infliximab or vedolizumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, vedolizumab treatment prior to 1 June 2018 may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response. Following the completion of an initial PBS-subsidised course, further subsidised treatment may be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment

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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 adalimumab, golimumab, infliximab or vedolizumab 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 adalimumab, golimumab, infliximab or vedolizumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab, vedolizumab treatment prior to 1 June 2018 may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response. Following the completion of an initial PBS-subsidised course, further subsidised treatment may 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.

**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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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply for Initial 1 and 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 insufficient therapy with this drug under the Initial 1 restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10); OR
- Patient must have received insufficient therapy with this drug under the Initial 2 restriction to complete 14 weeks of treatment (weeks 0, 2, 6 and 10).

**Population criteria:**

- Patient must be aged 18 years or older.

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**golimumab 100 mg/mL injection, 1 mL injection device**

**Authority required**

Non-radiographic axial spondyloarthitis

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 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 spondyloarthitis.

An adequate response to therapy with this drug 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 1-10) 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.

When a patient has either failed or ceased to respond to treatment with this drug for this condition twice, they must have, at a minimum, a 5-year break in PBS-subsidised treatment with this drug for this condition before they are eligible to recommence under the Initial 1 - New patient or recommencement after a break of more than 5 years. The 5-year break is measured from the approved date of the last prescription for PBS-subsidised treatment with this drug for this condition to the date of the first application for initial treatment under the Initial 1 restriction.

A patient who has failed treatment with this drug for this condition fewer than twice and who has a break in therapy of less than 5 years may re-commence a further course of treatment with this drug for this condition under the Initial 2 - Recomencement of treatment after a break of less than 5 years.

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.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Non-radiographic axial spondyloarthitis PBS Authority Application - Supporting Information including evidence of adequate response to therapy with PBS-subsidised golimumab.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001
**Authority required**

Non-radiographic axial spondyloarthritis

**Treatment Phase: Continuing and Grandfathered treatment - balance of supply**

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Initial 3 (grandfathered patient) restriction to complete 24 weeks of 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 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 non-radiographic axial spondyloarthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy, 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) Re-commencement of treatment after a break in therapy of less than 5 years’ below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.

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 recommencement of treatment after more than 5 years break in therapy); or
(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy): or
(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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
(iv) a patient wishes to re-commence 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 therapy 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 and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.
(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.

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.

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.

For second and subsequent continuing 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.

(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.

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 a 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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note No 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**

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:
1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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### Authority required
Severe psoriatic arthritis

**Treatment Phase:** Continuing treatment - balance of supply

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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### GOLIMUMAB

**Authority required**

Non-radiographic axial spondyloarthritis

**Treatment Phase:** Initial treatment 1 (New patients or recommencement after a break of more than 5 years)

**Clinical criteria:**
- Patient must not have received PBS-subsidised treatment with this drug for this condition in the last 5 years or more, **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 sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), **AND**

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#### golimumab 50 mg/0.5 mL injection, 0.5 mL injection device

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• 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) of at least 4 on a 0-10 scale; and
(b) 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.

CRP measure must be provided with the initial treatment application and must be no more than 1 month old at the time of application.

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

When a patient has either failed or ceased to respond to treatment with this drug for this condition twice, they must have, at a minimum, a 5-year break in PBS-subsidised treatment with this drug for this condition before they are eligible to recommence under the Initial 1 - New patient or recommencement after a break of more than 5 years.

The 5-year break is measured from the approved date of the last prescription for PBS-subsidised treatment with this drug for this condition to the date of the first application for initial treatment under the Initial 1 restriction.

A patient who has failed treatment with this drug for this condition fewer than twice and who has a break in therapy of less than 5 years may re-commence a further course of treatment with this drug for this condition under the Initial 2 - Re-commencement of treatment after a break of less than 5 years.

The authority application must include details of the contraindication according to the relevant TGA-approved Product Information

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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

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

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

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

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

Authority required
Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment 2 (Re-commencement of treatment after a break of less than 5 years)

Clinical criteria:
• Patient must have a documented history of non-radiographic axial spondyloarthritis, AND
• Patient must have received prior PBS-subsidised treatment with this drug for this condition within the last five years, AND
• Patient must not have failed PBS-subsidised treatment with this drug for this condition more than once within the last five years, 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.

An application for Initial 2 treatment must be accompanied by BASDAI and CRP results of the most recent course of treatment with this drug for this condition within the last 5 years to demonstrate a response to treatment. The results must be conducted following a minimum of 12 weeks of treatment.

When a patient has either failed or ceased to respond to treatment with this drug for this condition twice, they must have, at a minimum, a 5-year break in PBS-subsidised treatment with this drug for this condition before they are eligible to recommence under the Initial 1 - New patient or recommencement after a break of more than 5 years.

The 5-year break is measured from the approved date of the last prescription for PBS-subsidised treatment with this drug for this condition to the date of the first application for initial treatment under the Initial 1 restriction.

A patient who has failed treatment with this drug for this condition fewer than twice and who has a break in therapy of less than 5 years may re-commence a further course of treatment with this drug for this condition under the Initial 2 - Re-commencement of treatment after a break of less than 5 years.

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 PBS Authority Application - Supporting Information Form including:
   1. a completed BASDAI Assessment Form; and
   2. a copy of C-reactive protein (CRP) test result

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

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

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

Non-radiographic axial spondyloarthritis

**Treatment Phase:** Initial treatment 3 (grandfathered patient)

**Clinical criteria:**

• Patient must have previously received non-PBS subsidised therapy with this drug for this condition prior to 1 December 2018, AND
• Patient must have demonstrated an adequate response to non-PBS subsidised treatment with this drug for this condition, 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) dactylitis; (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, AND
• The condition must not be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, AND
• The condition must have been sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI), 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), AND
• The condition must have had BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium), 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 drug for this condition:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) 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 initiating non-PBS subsidised treatment with this drug for this condition.

CRP measurement must be provided with the initial treatment application and must be no more than 1 month old at the time of initiating non-PBS subsidised treatment with this drug for this condition.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

An adequate response to therapy with this drug 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 1-10) 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.

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:

(a) a completed authority prescription form; and

(b) a completed Non-radiographic axial spondyloarthritis Grandfathered PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming the absence of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; and

(ii) evidence of failure to achieve an adequate response to NSAIDs prior to initiating non-PBS subsidised golimumab for this condition; and

(iii) evidence of an adequate response to therapy with non-PBS subsidised golimumab for this condition following a minimum of 12 weeks of treatment with this drug for this condition; and

(iv) a copy of the MRI report; and

(v) details of the NSAIDs trialled, their doses and duration of treatment or 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 according to the relevant 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: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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

Non-radiographic axial spondyloarthritis

Treatment Phase: Initial treatment 1 and 2 - balance of supply

Clinical criteria:

• Patient must have received insufficient therapy with this drug under the Initial 1 (New patients or recommencement after a break of more than 5 years) restriction to complete 16 weeks treatment; OR

• Patient must have received insufficient therapy with this drug under the Initial 2 (Re-commencement 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.

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: 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).
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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the next cycle.

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.

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.

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.

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 recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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

(iv) a patient wishes to re-commence 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 therapy 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 and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

(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.

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. 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.

For second and subsequent continuing 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.

(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.

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 a 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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note
No 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 or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; **OR**
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
- either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.
Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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)

Clinical criteria:
• Patient must have a documented history of severe active psoriatic arthritis, AND
• Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND
• Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
• Patient must be an adult.

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:
• an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
• either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.
Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply
Clinical criteria:
• Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
• Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment, AND
• The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note 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

Mesalazine 1 g enteric tablet, 60
11554D

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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

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### methotrexate 15 mg/0.6 mL injection, 4 x 0.6 mL syringes

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### 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.

**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 20 mg/0.4 mL injection, 0.4 mL syringe

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### methotrexate 20 mg/0.8 mL injection, 4 x 0.8 mL syringes

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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.

### methotrexate 7.5 mg/0.15 mL injection, 0.15 mL syringe

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### methotrexate 7.5 mg/0.3 mL injection, 4 x 0.3 mL syringes

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### METHOTREXATE

**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.

**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 10 mg/0.4 mL injection, 4 x 0.4 mL syringes**

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**methotrexate 10 mg/0.2 mL injection, 0.2 mL syringe**

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### METHOTREXATE

**Note** Pharmaceutical benefits that have the form methotrexate Injection 25 mg/0.5 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 25 mg/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 25 mg/0.5 mL injection, 0.5 mL syringe**

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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.

**Authority required (STREAMLINED)**

8169
High grade serous ovarian 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 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.

**Authority required (STREAMLINED)**

8171
High grade serous fallopian tube 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 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.

Authority required (STREAMLINED)

8188
High grade serous primary peritoneal 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 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.

olaparib 150 mg tablet, 2 x 56
11539H
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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.

Authority required
High grade serous ovarian cancer
Treatment Phase: Initial treatment
Clinical criteria:
• The condition must be platinum sensitive, AND
• The condition must be a germline class 4 or 5 BRCA1 or BRCA2 gene mutation, 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 testing.

Authority required
High grade serous fallopian tube cancer
Treatment Phase: Initial treatment
Clinical criteria:
• The condition must be platinum sensitive, AND
• The condition must be a germline class 4 or 5 BRCA1 or BRCA2 gene mutation, 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 testing.

Authority required
High grade serous primary peritoneal cancer
Treatment Phase: Initial treatment
Clinical criteria:
• The condition must be platinum sensitive, **AND**
• The condition must be a germline class 4 or 5 BRCA1 or BRCA2 gene mutation, **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 testing.

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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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy, 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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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. 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 recommencement of treatment after more than 5 years break in therapy); or
   (ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or
   (iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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
   (iv) a patient wishes to re-commence 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 therapy 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 and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

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.

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. 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. For second and subsequent continuing 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.

(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.

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 trialed it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this treatment cycle with a 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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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.

(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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note 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

Note No 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 or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencing treatment after a break of less than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete maximum of 16 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencing treatment after a break of less than 5 years) 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.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**secukinumab 150 mg/mL injection, 2 x 1 mL injection 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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy. 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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.

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 recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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

(iv) a patient wishes to re-commence 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 therapy 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 and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

(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.

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. 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.

For second and subsequent continuing 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.

(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.

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 a 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 treatment application is
submitted within a treatment cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the
commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient
must have received treatment with methotrexate and sulfasalazine or lefunomide, at an adequate dose, for a minimum of 3
months at the time the ESR or CRP levels and the active joint counts are measured.

Note No 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

Clinical criteria:
• Patient must have a documented history of severe active psoriatic arthritis, AND
• Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for
  this condition in the current Treatment Cycle, AND
• Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND
• Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this
  restriction.

Population criteria:
• Patient must be an adult.

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab,
infliximab, secukinumab or ustekinumab.
An adequate response to treatment is defined as:
an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than
15 mg per L or either marker reduced by at least 20% from baseline; and
either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20
active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and
limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
The same indices of disease severity used to establish baseline at the commencement of treatment with each initial
treatment application must be provided for all subsequent continuing treatment applications.
All applications for continuing treatment with this drug must include a measurement of response to the most recent course of
PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment
course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an
assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.
Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to
respond to treatment with this drug.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive
further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5
years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle
and the date of the first application under the new Cycle.

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

Severe active psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.

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 recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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

(iv) a patient wishes to re-commence 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 therapy 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 and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

(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.

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. 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.

For second and subsequent continuing 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.

(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.

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 a 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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note The assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

- Patient must have severe active psoriatic arthritis, AND
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND
• Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
• Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
• Patient must be an adult.

Treatment criteria:
• Must be treated by a rheumatologist; OR
• Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
either
(a) an active joint count of at least 20 active (swollen and tender) joints; or
(b) at least 4 active joints from the following list of major joints:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 recommencing treatment after a break of less than 5 years )

Clinical criteria:
• Patient must have a documented history of severe active psoriatic arthritis, AND
• Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
• Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND
• Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
• Patient must be 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.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.
Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

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

secukinumab 150 mg/mL injection, 2 x 1 mL injection devices

10894J

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

4 .. .. *6193.13 39.50 Cosentyx [NV]

secukinumab 150 mg/mL injection, 1 mL injection device

10900Q

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

4 .. .. *3172.09 39.50 Cosentyx [NV]

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 an SGLT2 inhibitor; or

- 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) 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 25 mg tablet, 28**

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**Sitagliptin 100 mg tablet, 28**

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- **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 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** 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) 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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**Sitagliptin 25 mg tablet, 28**

**9180E**

Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN  | Brand Name and Manufacturer
---|---|---|---|---|---
1 | 5 | .. | 56.62 | 39.50 | Januvia [MK]

**Sitagliptin 100 mg tablet, 28**

**9182G**

Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN  | Brand Name and Manufacturer
---|---|---|---|---|---
1 | 5 | .. | 56.62 | 39.50 | Januvia [MK]

**Sitagliptin 50 mg tablet, 28**

**9181F**

Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN  | Brand Name and Manufacturer
---|---|---|---|---|---
1 | 5 | .. | 56.62 | 39.50 | Januvia [MK]

**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 glitazone with a glitazone; or
- an SGLT2 inhibitor with a glitazone.

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**Authority required (STREAMLINED)**

**7500**

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 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 glitazone with a glitazone; or
- an SGLT2 inhibitor with a glitazone.
• 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
of 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 + 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 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 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:**

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General Pharmaceutical Benefits

69
- 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 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)**

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.

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

**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 gliptin with a glitazone; or
• an SGLT2 inhibitor with a glitazone.

### Sitagliptin 50 mg + Metformin Hydrochloride 1 g Modified Release Tablet, 56

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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). Patients are 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.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 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 without having to requalify under the Initial 1 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 must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised 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 August 2010.

(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 patient recommencing treatment after a break of more than 24 months); or
(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 1 - new patient or patient recommencing treatment after a break of more than 24 months); or
(iii) 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 of less than 24 months) [further details are under 'Swapping therapy' below]; or
(iv) 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 of less than 24 months).

Initial applications for new or re-commencing patients (Initial 1 - new patient or patient recommencing treatment after a break of more than 24 months) 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 and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab. A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks...
after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) 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.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the 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 the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific 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 demonstrate a response according 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. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that 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. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate 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:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, 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.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note No 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 a documented history of severe active rheumatoid arthritis, AND
- Patient must have demonstrated an adequate response to treatment with tocilizumab, AND
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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

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 authority application must be made in writing and must include:
- (1) completed authority prescription form(s); and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

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

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

Applications for authority to prescribe should be forwarded to:
Department of Human Services
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 tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL injection 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) 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).

Patients are 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.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 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 without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 biological medicines and who has a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised 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 August 2010.

(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 patient recommencing treatment after a break of more than 24 months); or
(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 1 - new patient or patient recommencing treatment after a break of more than 24 months); or
(iii) 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 of less than 24 months) [further details are under ‘Swapping therapy’ below]; or
(iv) 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 of less than 24 months).

Initial applications for new or re-commencing patients (Initial 1 - new patient or patient recommencing treatment after a break of more than 24 months) 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 and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine. For second and subsequent courses of PBS-subsidised biological medicine (excluding rituximab) 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.

Abatacept patients:

- Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the 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 the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific 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.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that 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. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each biological medicine trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate 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:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

Rituximab:
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment, 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.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

Note: Special Pricing Arrangements apply.
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 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.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate.

The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs 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 treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Rheumatoid Arthritis initial PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement. If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose; (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial; (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break 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 rheumatoid arthritis, AND
• Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND
• Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
• Patient must be aged 18 years or older.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include: (a) completed authority prescription form(s); and (b) a completed Rheumatoid Arthritis continuing PBS Authority Application - Supporting Information Form. Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased. Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab. If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) - balance of supply

**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 tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**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).

tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL injection devices

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tocilizumab 162 mg/0.9 mL injection, 4 x 0.9 mL syringes

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**TRIFLURIDINE + TIPIRACL**

**Note** No increase 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)**

**8195**

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.

Authority required (STREAMLINED)

8183
Metastatic colorectal cancer
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 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.

trifluridine 15 mg + tipiracil 6.14 mg tablet, 20
11507P

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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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.

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 recommencement of treatment after more than 5 years break in therapy); or
(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or
(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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
(iv) a patient wishes to re-commence 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 therapy 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 and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing.
regimen), 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.

(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.

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. 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.

For second and subsequent continuing 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.

(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.

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 a 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 treatment application is ongoing. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level 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.

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 a 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.

(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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

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 a documented history of severe active psoriatic arthritis, AND
- Patient must have been receiving treatment with this drug for this condition prior to 1 May 2016, AND
- Patient must be receiving treatment with this drug for this condition at the time of application, AND
- Patient must have demonstrated a response to treatment as specified in the criteria for continuing PBS-subsidised treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be an adult.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

A patient may qualify for PBS-subsidised treatment under this restriction once only.
Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

Note Special Pricing Arrangements apply.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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

Clinical criteria:
- Patient must have a documented history of severe active psoriatic arthritis, AND
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:
- Patient must be an adult.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.
An adequate response to treatment is defined as:
- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
     (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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
General Pharmaceutical Benefits

USTEKINUMAB

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

10767Q

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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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

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) Re-commencement of treatment after a break in therapy of less than 5 years].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.

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 recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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

(iv) a patient wishes to re-commence 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 therapy 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, infliximab, secukinumab and ustekinumab only.
etanercept and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

(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. 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. 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. For second and subsequent continuing 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.

(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.

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 a 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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required
Severe psoriatic arthritis
Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

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 severe active psoriatic arthritis, AND
• Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
• Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND
• Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND
• Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
• Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND
• Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:
• Patient must be an adult.
For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.
Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
- either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au).

**Note** The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Note** Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

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

**Note** Special Pricing Arrangements apply.

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

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**

**Severe psoriatic arthritis**

**Treatment Phase:** Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**

- Patient must have a documented history of severe active psoriatic arthritis, AND
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.
Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

- The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

- 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)

- Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

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

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

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

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

- Special Pricing Arrangements apply.

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<td>• Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR</td>
</tr>
<tr>
<td>• Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 28 weeks treatment. AND</td>
</tr>
<tr>
<td>• The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions.</td>
</tr>
</tbody>
</table>

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

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.

**Ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial**

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Palliative Care

- **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.

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<td>Clinical criteria:</td>
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<td>• Patient must be receiving palliative care.</td>
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Highly Specialised Drugs Program (Private Hospital)

**BENRALIZUMAB**

**Note**: TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA

Patients are eligible to commence a 'benralizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to benralizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised benralizumab therapy before they are eligible to commence the next 'benralizumab treatment cycle', or if eligible, a ‘mepolizumab treatment cycle’ or an ‘omalizumab treatment cycle’. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised benralizumab is stopped to the date of the first application for initial treatment with benralizumab, mepolizumab or omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised benralizumab therapy:

(a) Initial treatment:
Applications for initial treatment should be made where:

i) A patient has received no prior PBS-subsidised benralizumab treatment and wishes to commence such therapy; or

ii) A patient wishes to recommence treatment with benralizumab following a break in PBS-subsidised therapy of more than 6 months; or

iii) A patient has received prior PBS-subsidised mepolizumab or omalizumab and wishes to commence treatment with benralizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of up to 32 weeks of therapy for benralizumab.

(b) Grandfather patients:

For patients who commenced treatment with non-PBS subsidised benralizumab for uncontrolled severe eosinophilic asthma prior to 1 December 2018 and who continue to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with benralizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with benralizumab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a ‘Grandfathered’ patient recommences on second and subsequent cycles after a treatment break, the ‘Grandfathered’ patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 6 month break in PBS-subsidised therapy’ below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with benralizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with benralizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing benralizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose, submitted with the Initial authority application for benralizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent benralizumab treatment cycle, or an initial mepolizumab or omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

**Note**: No increase 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**

Uncontrolled severe eosinophilic asthma

**Treatment Phase**: Initial treatment

**Treatment criteria:**
Highly Specialised Drugs Program (Private Hospital)

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of adherence to correct inhaler technique, which has been documented, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab or mepolizumab.

**Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**
(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient must be made at time of application for treatment (to establish baseline score) and again 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the assessment at the time of the application to be processed.

This assessment at around 24 weeks, which will be used to determine eligibility for the first continuing treatment, must be submitted no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

A patient who fails to respond to a course of PBS-subsidised benralizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with benralizumab, mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course of benralizumab sufficient for up to 32 weeks of therapy, at a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter.

Benralizumab must not be used concurrently with omalizumab or mepolizumab or within 6 months of each other. A patient is required to have ceased treatment with omalizumab or mepolizumab for 6 months prior to initiating treatment with benralizumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:

(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(c) a copy of the eosinophil pathology report; and
(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient’s symptoms.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.
Note For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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

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).

Authority required

Uncontrolled severe eosinophilic asthma
Treatment Phase: Initial treatment - balance of supply

Treatment criteria:
- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma

Clinical criteria:
- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 32 weeks treatment; AND
- The treatment must provide no more than the balance of up to 32 weeks treatment available under the Initial restriction.

Population criteria:
- Patient must be aged 12 years or older.

Note Authority approval for sufficient therapy to complete a maximum of 32 weeks of treatment under the initial restriction 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).

benralizumab 30 mg/mL injection, 1 mL syringe

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BENRALIZUMAB

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASThma

Patients are eligible to commence a ‘benralizumab treatment cycle’ (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to benralizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised benralizumab therapy before they are eligible to commence the next ‘benralizumab treatment cycle’, or if eligible, a ‘mepolizumab treatment cycle’ or an ‘omalizumab treatment cycle’. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised benralizumab is stopped to the date of the first application for initial treatment with benralizumab, mepolizumab or omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised benralizumab therapy:

(a) Initial treatment:
Applications for initial treatment should be made where:
- i) A patient has received no prior PBS-subsidised benralizumab treatment and wishes to commence such therapy; or
- ii) A patient wishes to recommence treatment with benralizumab following a break in PBS-subsidised therapy of more than 6 months; or
- iii) A patient has received prior PBS-subsidised mepolizumab or omalizumab and wishes to commence treatment with benralizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of up to 32 weeks of therapy for benralizumab.

(b) Grandfather patients:

For patients who commenced treatment with non-PBS subsidised benralizumab for uncontrolled severe eosinophilic asthma prior to 1 December 2018 and who continue to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with benralizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with benralizumab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a ‘Grandfathered’ patient recommences on second and subsequent cycles after a treatment break, the ‘Grandfathered’ patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 6 month break in PBS-subsidised therapy’ below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with benralizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with benralizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing benralizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose, submitted with the Initial authority application for benralizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent benralizumab treatment cycle, or an initial mepolizumab or omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

Note No increase 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
Uncontrolled severe eosinophilic asthma
Treatment Phase: Continuing treatment

Treatment criteria:
- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, AND
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab or mepolizumab.

Population criteria:
- Patient must be aged 12 years or older.
An adequate response to benralizumab treatment is defined as:
(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline; OR
(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, or the assessment of oral corticosteroid dose, should be made at around 16 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 2 weeks prior to the patient completing their current treatment course to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

A patient who fails to respond to a course of PBS-subsidised benralizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with benralizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Eosinophilic Asthma Continuing PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; or a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

Note If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.
Note For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.
Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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
Uncontrolled severe eosinophilic asthma
Treatment Phase: Continuing treatment or Grandfathered treatment - balance of supply

Treatment criteria:
- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:
• Patient must have received insufficient therapy with this drug under the continuing treatment restriction or the grandfather 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.

**Population criteria:**
• Patient must be aged 12 years or older.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Uncontrolled severe eosinophilic asthma  
Treatment Phase: Grandfathered treatment

**Treatment criteria:**
• Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**
• Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2018, AND
• Patient must be receiving treatment with this drug for this condition at the time of application, AND
• Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, AND
• Patient must have had, prior to commencement of non-PBS subsidised treatment with this drug, a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than or equal to 15% between the two highest and two lowest peak expiratory flow rates during 14 days, AND
• Patient must have had blood eosinophil count greater than or equal to 300 cells per microlitre prior to commencement of non-PBS subsidised treatment with this drug, AND
• Patient must have had a duration of asthma of at least 1 year prior to commencement of non-PBS subsidised treatment with this drug, AND
• Patient must have failed to achieve adequate control with optimised asthma therapy prior to non-PBS subsidised treatment with this drug despite formal assessment of and adherence to correct inhaler technique, which has been documented, AND
• Patient must have demonstrated an adequate response following at least 24 weeks of treatment of non-PBS subsidised benralizumab or mepolizumab for this condition, AND
• The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab or mepolizumab.

**Population criteria:**
• Patient must be aged 12 years or older.

Optimised asthma therapy includes:
(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND
(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, prior to commencing non-PBS subsidised treatment with this drug, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

An adequate response to benralizumab treatment is defined as:
(a) a reduction in the Asthma Control Questionnaire (ACQ 5) score of at least 0.5 from baseline; OR
(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ 5 score from baseline.

A multidisciplinary severe asthma clinic team comprises of:
• A respiratory physician; and
• A pharmacist, nurse or asthma educator.

A review of the patient's records should be conducted to extract pre- and post-benralizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Parameters to establish response are:
(i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5; and/or
(ii) maintenance oral corticosteroid dose reduced by at least 25% from baseline and no deterioration in ACQ 5 score from baseline.

The assessment of the patient's response to the initial PBS-subsidised course of treatment under this restriction must be made at around 16 weeks after the first dose of PBS-subsidised treatment with this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The
same parameters used to establish response to non-PBS subsidised therapy with this drug should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

Patients will be eligible to receive continuing courses of treatment with this drug of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

A patient who fails to respond to a course of PBS-subsidised benralizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with benralizumab, omalizumab or mepolizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of benralizumab sufficient for up to 24 weeks of therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Eosinophilic Asthma Grandfather PBS Authority Application - Supporting Information Form, which includes the following:
   (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
   (ii) details of pre- and post-benralizumab data on symptoms, quality of life, medication doses, severe exacerbation/s and hospitalisations; and
(c) a copy of the pre-benralizumab eosinophil pathology report; and
(d) a completed Asthma Control Questionnaire (ACQ 5) calculation sheet including the date of assessment of the patient's symptoms; or details of maintenance oral corticosteroid dose.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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

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).

benralizumab 30 mg/mL injection, 1 mL syringe

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**DEFERASIROX**

Note Pharmaceutical benefits that have the form deferasirox 500 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 360 mg film coated tablet are equivalent for the purposes of substitution.

Note Special Pricing Arrangements apply.

**Authority required**

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:
- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

**Authority required**

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:
- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

**deferasirox 360 mg tablet, 30**

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**DEFERASIROX**

*Note* Pharmaceutical benefits that have the form deferasirox 125 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 90 mg film coated tablet are equivalent for the purposes of substitution.

*Note* Special Pricing Arrangements apply.

**Authority required**

Chronic iron overload

**Clinical criteria:**
- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

**Authority required**

Chronic iron overload

**Clinical criteria:**
- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

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**DEFERASIROX**

*Note* Pharmaceutical benefits that have the form deferasirox 250 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 180 mg film coated tablet are equivalent for the purposes of substitution.

*Note* Special Pricing Arrangements apply.

**Authority required**

Chronic iron overload

**Clinical criteria:**
- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

**Authority required**

Chronic iron overload

**Clinical criteria:**
- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

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**DEFERASIROX**

*Note* Pharmaceutical benefits that have the form deferasirox 250 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 180 mg film coated tablet are equivalent for the purposes of substitution.

*Note* Special Pricing Arrangements apply.

**Authority required**

Chronic iron overload

**Clinical criteria:**
- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.

**Authority required**
Chronic iron overload
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia, **AND**
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.

**Authority required**

Chronic iron overload
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.

**Note**

Interruption of treatment should be considered if serum ferritin levels fall consistently below 500 microgram/ml.

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**Deferasirox 250 mg dispersible tablet, 28**

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**Deferasirox**

Note: Pharmaceutical benefits that have the form deferasirox 500 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 360 mg film coated tablet are equivalent for the purposes of substitution.

**Note**

Special Pricing Arrangements apply.

**Note**

A patient's median life expectancy is determined by the severity of their underlying disease.

**Note**

Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:
- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

**Note**

Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:
- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

**Authority required**

Chronic iron overload
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

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**Deferasirox 360 mg tablet, 30**

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**Deferasirox 500 mg dispersible tablet, 28**

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**Deferasirox**

Note: Pharmaceutical benefits that have the form deferasirox 500 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 360 mg film coated tablet are equivalent for the purposes of substitution.

**Note**

Special Pricing Arrangements apply.

**Authority required**

Chronic iron overload
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must not be transfusion dependent, AND
- The condition must be thalassaemia, AND
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.

Authority required

Information on iron overload

Note
- Interruption of treatment should be considered if serum ferritin levels fall consistently below 500 microgram/ml.

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DEFERASIROX

Note
- Pharmaceutical benefits that have the form deferasirox 125 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 90 mg film coated tablet are equivalent for the purposes of substitution.

Note
- Special Pricing Arrangements apply.

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DEFERASIROX

Note
- Pharmaceutical benefits that have the form deferasirox 250 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 180 mg film coated tablet are equivalent for the purposes of substitution.

Note
- Special Pricing Arrangements apply.

Note
- A patient's median life expectancy is determined by the severity of their underlying disease.

Note
- Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:
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**Note**
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- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
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**DEFERASIROX**

**Note**
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**FILGRASTIM**

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, AND
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, AND
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.
Mobilisation of peripheral blood progenitor cells

Clinical criteria:
- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required
Mobilisation of peripheral blood progenitor cells

Clinical criteria:
- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required
Assisting bone marrow transplantation

Clinical criteria:
- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority required
Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:
- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority required
Severe congenital neutropenia

Clinical criteria:
- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, AND
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority required
Severe chronic neutropenia

Clinical criteria:
- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, AND
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority required
Chronic cyclical neutropenia

Clinical criteria:
- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, AND
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes

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filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes

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filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes

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filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

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filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

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INFLIXIMAB

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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol,
etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.

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 recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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

(iv) a patient wishes to re-commence 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 therapy 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 and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

(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.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

A patient must be assessed for response to a course of continuing therapy to ensure uninterrupted biological medicine supply. For second and subsequent continuing 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.

(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.

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 a 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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the
commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or lefunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

### Authority required

Severe psoriatic arthritis

Treatment Phase: 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 psoriatic 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 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.

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.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

### infliximab 100 mg injection, 1 vial

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**INFILXIMAB**

**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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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. 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. 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 recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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

(iv) a patient wishes to re-commence 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 therapy 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 and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

(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.

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. 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.

For second and subsequent continuing 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.

(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.

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 a 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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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
Authority required
Severe psoriatic 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 psoriatic 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.

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; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

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.

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 must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

infliximab 100 mg injection, 1 vial

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INFLIXIMAB

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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.
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 recommencement of treatment after more than 5 years break in therapy); or
(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of
more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or
(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an
alternate medicine (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
(iv) a patient wishes to re-commence 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
therapy 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 and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing
regimen), 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.

(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.
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.
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.
For second and subsequent continuing 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.

(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.
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 a 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 treatment application is
submitted within a treatment cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the
commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient
must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3
months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**
Severe psoriatic arthritis
Treatment Phase: Initial 1 (new patient or recommencement of treatment after more than 5 years break in therapy)

**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 prior PBS-subsidised treatment with a biological medicine for this condition; OR
• Patient must not have received PBS-subsidised treatment with a biological medicine for this condition in the previous 5 years, AND
• Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND
• Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
• Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND
• Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**
• Patient must be 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; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be conducted no later than 1 month from the date of completion of this initial course of treatment.

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 issued in this cycle and the date of the first application under a new cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note Biosimilar preferred prescribing policy**
Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** 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 the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 2 (change or recommencement of treatment after a break in therapy of less then 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 22 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:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

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).

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.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be conducted no later than 1 month from the date of completion of this initial course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was accessed under the first continuing or subsequent continuing treatment restriction, the patient must have been assessed for response.

Where a response assessment is not undertaken the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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 issued in this cycle and the date of the first application under a new cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusion at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

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

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

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

**Authority required**
Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient or recommencement of treatment after more than 5 years break in therapy) or 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 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 or recommencement of treatment after more than 5 years break in therapy) restriction to complete 22 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 therapy of less than 5 years) restriction to complete 22 weeks treatment, AND
• The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

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

**Note**
Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Authority required
Severe psoriatic 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 psoriatic arthritis.

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.

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; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.
The application for first continuing treatment following an initial treatment course must be made following a minimum of 12
weeks of treatment with this drug. This assessment must be conducted no later than 4 weeks from the cessation of that
treatment course.
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 issued in this cycle
and the date of the first application under a new cycle.
At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the
weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.
Up to a maximum of 2 repeats will be authorised.

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

Authority required
Severe psoriatic 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 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.

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

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone
by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to
Friday).

infliximab 100 mg injection, 1 vial

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</tbody>
</table>

* Remicade [JC]
**LANREOTIDE**

**Note** No 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-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

**Clinical criteria:**
- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be as monotherapy.

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

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

Lanreotide is not PBS-subsidised for use in combination with everolimus or sunitinib for this condition.

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<tr>
<th>Lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe</th>
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<tr>
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**LENOGRASTIM**

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving first-line chemotherapy for Hodgkin disease, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), **AND**
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, **AND**
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.

**Authority required**
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.
Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade).

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma.

Authority required

Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma.

Authority required

Mobilisation of peripheral blood progenitor cells

Clinical criteria:
- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority required

Mobilisation of peripheral blood progenitor cells

Clinical criteria:
- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority required

Assisting peripheral blood progenitor cell or bone marrow transplantation

Clinical criteria:
- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

lenograstim 13.4 million units (105 microgram) injection, 1 vial

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lenograstim 33.6 million units (263 microgram) injection, 1 vial

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MEPOLIZUMAB

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA

Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction. Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, a 'benralizumab treatment cycle' or an 'omalizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with benralizumab, mepolizumab or omalizumab under the new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised mepolizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where:
   i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or
   ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or
   iii) A patient has received prior PBS-subsidised benralizumab or omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy for mepolizumab.

(b) Continuing treatment:
Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when
a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial benralizumab or omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

Note No increase 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 If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.
Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.
Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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
Uncontrolled severe eosinophilic asthma
Treatment Phase: Continuing treatment

Treatment criteria:
• Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:
• Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition. AND
• The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised benralizumab or omalizumab.

Population criteria:
• Patient must have been aged 12 years or older.
An adequate response to mepolizumab treatment is defined as:
(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR
(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient’s response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made at around 18 to 22 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS subsidised treatment with mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Eosinophilic Asthma Continuing PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; or a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of the assessment of the patient's symptoms.

mepolizumab 100 mg injection, 1 vial

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**MEPOLIZUMAB**

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA
 Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a
treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, a 'benralizumab treatment cycle' or an 'omalizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with benralizumab, mepolizumab or omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised mepolizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where:
(i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or
(ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or
(iii) A patient has received prior PBS-subsidised benralizumab or omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy for mepolizumab.
(b) Continuing treatment:
Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial benralizumab or omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

**Note**
No increase 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**
The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note**
For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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

**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).

**Authority required**
Uncontrolled severe eosinophilic asthma

**Treatment Phase: Initial treatment**

**Treatment criteria:**
- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**
- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
• Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months, AND
• Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, AND
• The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised benralizumab or omalizumab.

Population criteria:
• Patient must be aged 12 years or older.

Optimised asthma therapy includes:
(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND
(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:
(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND
(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient must be made at time of application for treatment (to establish baseline score) and again around 26 to 30 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 26 to 30 weeks, which will be used to determine eligibility for the first continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with benralizumab, mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of mepolizumab sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:
• A respiratory physician; and
• A pharmacist, nurse or asthma educator.

Mepolizumab must not be used concurrently with benralizumab or omalizumab, or within 6 months of each other. A patient is required to have ceased treatment with benralizumab or omalizumab for 6 months prior to initiating treatment with mepolizumab.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:
(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
(c) a copy of the eosinophil pathology report; and
(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient’s symptoms.

**Popledizumab 100 mg injection, 1 vial**

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**MIDOSTAURIN**

Note: No increase 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 authority to prescribe may be made by phone 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**

Acute Myeloid Leukaemia

Treatment Phase: Induction / Consolidation therapy

**Clinical criteria:**

• Patient must not have received prior chemotherapy as induction therapy for this condition; OR
• The treatment must be for consolidation treatment following induction treatment with midostaurin in combination with chemotherapy, AND
• The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition, **AND**
• The condition must not be acute promyelocytic leukaemia, **AND**
• The treatment must be in combination with standard intensive remission induction or consolidation chemotherapy for this condition.

A maximum of 6 cycles will be authorised under this restriction in a lifetime.

Standard intensive remission induction combination chemotherapy must include cytarabine and an anthracycline.

The FLT3 ITD or TKD mutation test result and date of testing must be provided at the time of application.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5% blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**midostaurin 25 mg capsule, 56**

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**MIDOSTAURIN**

**Note** No increase 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 authority to prescribe may be made by phone 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**

Acute Myeloid Leukaemia

Treatment Phase: Maintenance therapy - Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial maintenance or the initial maintenance grandfathering treatment restriction, **AND**
- Patient must not have developed disease progression while receiving PBS subsidised treatment with this drug for this condition, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant.

A maximum of 9 cycles will be authorised under this restriction in a lifetime.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5% blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**midostaurin 25 mg capsule, 112**

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**MIDOSTAURIN**

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

**Note** Special Pricing Arrangements apply.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Authority required
Acute Myeloid Leukaemia
Treatment Phase: Maintenance therapy - Initial treatment

Clinical criteria:
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated complete remission after induction and consolidation chemotherapy in combination with midostaurin, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant, **AND**
- The condition must have been internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition.

A maximum of 3 cycles will be authorised under this restriction in a lifetime.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:
- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The authority application must be made in writing and must include:
1. a completed authority prescription form;
2. a completed Acute myeloid leukaemia PBS Authority Application - Supporting Information Form; and
3. confirmation that the patient is not undergoing or has not undergone a stem cell transplant; and
4. confirmation that the patient does not have progressive disease; and
5. a copy of a recent bone marrow biopsy report demonstrating that the patient is in complete remission; and
6. a copy of the pathology test demonstrating that the condition was FMS tyrosine kinase 3 (FLT3) (ITD or TKD) mutation positive prior to commencing midostaurin.

midostaurin 25 mg capsule, 112

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**MIDOSTAURIN**

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**Note** No increase in the maximum number of repeats may be authorised.
**Note** Special Pricing Arrangements apply.

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

Authority required
Acute Myeloid Leukaemia
Treatment Phase: Maintenance therapy - Grandfathered treatment

Clinical criteria:
- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2018, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must have demonstrated complete remission after induction and consolidation chemotherapy in combination with midostaurin, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant, **AND**
- The condition must have been internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition.

A maximum of 2 cycles will be authorised under this restriction in a lifetime.

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 maintenance therapy continuing treatment criteria.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:
- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5% blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The authority application must be made in writing and must include:
1. a completed authority prescription form;
2. a completed Acute myeloid leukaemia PBS Authority Application - Supporting Information Form; and
3. confirmation that the patient does not have progressive disease; and
4. a copy of a recent bone marrow biopsy report demonstrating that the patient is in complete remission; and
5. a copy of the pathology test demonstrating that the condition was FMS tyrosine kinase 3 (FLT3) (ITD or TKD) mutation positive prior to commencing midostaurin.

### midostaurin 25 mg capsule, 112

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### OCTREOTIDE

**Authority required**

**Acromegaly**

**Clinical criteria:**
- The condition must be controlled with octreotide immediate release injections, AND
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), AND
- The treatment must cease if IGF1 is not lower after 3 months of treatment, AND
- The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required**

**Functional carcinoid tumour**

**Clinical criteria:**
- Patient must have achieved symptom control on octreotide immediate release injections, AND
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required**

**Vasoactive intestinal peptide secreting tumour (VIPoma)**

**Clinical criteria:**
- Patient must have achieved symptom control on octreotide immediate release injections, AND
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

### octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

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### octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

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### octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

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OCTREOTIDE

**Authority required**

Acromegaly

**Clinical criteria:**
- The condition must be active, AND
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, AND
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, AND
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**
- The condition must be causing intractable symptoms, AND
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, AND
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, AND
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**OCTREOTIDE**

**Clinical criteria:**
- The condition must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery where radiotherapy is contraindicated, AND
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, AND
- The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, AND
- The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

**Authority required**

Functional carcinoid tumour

**Clinical criteria:**
- The condition must be causing intractable symptoms, AND
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, AND
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, AND
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**OMALIZUMAB**

**Note**

TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an ‘omalizumab treatment cycle’ (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a ‘benralizumab treatment cycle’ or a ’mepolizumab treatment cycle’. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab is stopped to the date of the first application for initial treatment with benralizumab, omalizumab or mepolizumab.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where:
i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or
ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or

iii) A patient has received prior PBS-subsidised benralizumab or mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.

All applications for initial treatment will be limited to provide for a maximum of up to 28 weeks of therapy of omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial benralizumab or mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Special Pricing Arrangements apply.

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

Treatment criteria:

• Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

• Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, AND

• Patient must have a duration of asthma of at least 1 year,

• Patient must have past or current evidence of atopy, documented by skin prick testing or RAST, AND

• Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, AND

• Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, AND

• Patient must not receive more than 28 weeks of treatment under this restriction, AND

• The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised benralizumab or mepolizumab.

Population criteria:

• Patient must be aged 12 years or older.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND
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).

The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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

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).

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe allergic asthma, AND
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, AND
- Patient must not receive more than 24 weeks of treatment under this restriction, AND
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised benralizumab or mepolizumab.

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR
omalizumab 150 mg/mL injection, 1 mL syringe

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omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

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Highly Specialised Drugs Program (Public Hospital)

**BENRALIZUMAB**

**Note** TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASThma

Patients are eligible to commence a ‘benralizumab treatment cycle’ (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to benralizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised benralizumab therapy before they are eligible to commence the next ‘benralizumab treatment cycle’, or if eligible, a ‘mepolizumab treatment cycle’ or an ‘omalizumab treatment cycle’. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised benralizumab is stopped to the date of the first application for initial treatment with benralizumab, mepolizumab or omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised benralizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

i) A patient has received no prior PBS-subsidised benralizumab treatment and wishes to commence such therapy; or

ii) A patient wishes to recommence treatment with benralizumab following a break in PBS-subsidised therapy of more than 6 months; or

iii) A patient has received prior PBS-subsidised mepolizumab or omalizumab and wishes to commence treatment with benralizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of up to 32 weeks of therapy for benralizumab.

(b) Grandfather patients:

For patients who commenced treatment with non-PBS subsidised benralizumab for uncontrolled severe eosinophilic asthma prior to 1 December 2018 and who continue to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with benralizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the Initial PBS-subsidised course, further applications for treatment with benralizumab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a ‘Grandfathered’ patient recommences on second and subsequent cycles after a treatment break, the ‘Grandfathered’ patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 6 month break in PBS-subsidised therapy’ below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with benralizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with benralizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing benralizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose, submitted with the Initial authority application for benralizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent benralizumab treatment cycle, or an initial mepolizumab or omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

**Note** No increase 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

Uncontrolled severe eosinophilic asthma

Treatment Phase: Initial treatment

Treatment criteria:
• Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:
• Patient must be under the care of the same physician for at least 6 months; OR
• Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, AND
• Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, AND
• Patient must have a duration of asthma of at least 1 year, AND
• Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, AND
• Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months, AND
• Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, AND
• The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab or mepolizumab.

Population criteria:
• Patient must be aged 12 years or older.

Optimised asthma therapy includes:
(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND
(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:
(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND
(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient must be made at time of application for treatment (to establish baseline score) and again around 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 24 weeks, which will be used to determine eligibility for the first continuing treatment, must be submitted no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

A patient who fails to respond to a course of PBS-subsidised benralizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with benralizumab, mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.

A multidisciplinary severe asthma clinic team comprises of:
• A respiratory physician; and
• A pharmacist, nurse or asthma educator.

At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course of benralizumab sufficient for up to 32 weeks of therapy, at a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter.

Benralizumab must not be used concurrently with omalizumab or mepolizumab or within 6 months of each other. A patient is required to have ceased treatment with omalizumab or mepolizumab for 6 months prior to initiating treatment with benralizumab.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:
(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
(c) a copy of the eosinophil pathology report; and
(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient’s symptoms.

Note: The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.
benralizumab 30 mg/mL injection, 1 mL syringe

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\**BENRALIZUMAB**

\**Note**: Treatment of Adult and Adolescent Patients with Uncontrolled Severe Eosinophilic Asthma

Patients are eligible to commence a ‘benralizumab treatment cycle’ (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to benralizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised benralizumab treatment before they are eligible to commence the next ‘benralizumab treatment cycle’, or if eligible, a ‘mepolizumab treatment cycle’ or an ‘omalizumab treatment cycle’. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised benralizumab is stopped to the date of the first application for initial treatment with benralizumab, mepolizumab or omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised benralizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

(i) A patient has received no prior PBS-subsidised benralizumab treatment and wishes to commence such therapy; or

(ii) A patient wishes to recommence treatment with benralizumab following a break in PBS-subsidised therapy of more than 6 months; or

(iii) A patient has received prior PBS-subsidised mepolizumab or omalizumab and wishes to commence treatment with benralizumab after a treatment break of 6 months.

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of up to 32 weeks of therapy for benralizumab.

(b) Grandfather patients:

For patients who commenced treatment with non-PBS subsidised benralizumab for uncontrolled severe eosinophilic asthma prior to 1 December 2018 and who continue to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction. A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment with benralizumab will be authorised under this criterion. Approval will be based on the criteria included in the relevant restriction. Following completion of the initial PBS-subsidised course, further applications for treatment with benralizumab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). If a ‘Grandfathered’ patient recommences on second and subsequent cycles after a treatment break, the ‘Grandfathered’ patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' below for further details.

(c) Continuing treatment:

Following the completion of the initial treatment course with benralizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with benralizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing benralizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose, submitted with the Initial authority application for benralizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

3 Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent benralizumab treatment cycle, or an initial mepolizumab or omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

Note No increase 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
Uncontrolled severe eosinophilic asthma
Treatment Phase: Continuing treatment

Treatment criteria:
- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, AND
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab or mepolizumab.

Population criteria:
- Patient must be aged 12 years or older.
An adequate response to benralizumab treatment is defined as:
(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline; OR
(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, or the assessment of oral corticosteroid dose, should be made at around 16 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

A patient who fails to respond to a course of PBS-subsidised benralizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with benralizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Eosinophilic Asthma Continuing PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; or a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

Note If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.
Note For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.
Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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
Uncontrolled severe eosinophilic asthma
Treatment Phase: Continuing treatment or Grandfathered treatment - balance of supply

Treatment criteria:
- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:
• Patient must have received insufficient therapy with this drug under the continuing treatment restriction or the grandfather 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.

**Population criteria:**
• Patient must be aged 12 years or older.

**Note** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Uncontrolled severe eosinophilic asthma

**Treatment Phase:** Grandfathered treatment

**Treatment criteria:**
• Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**
• Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2018, **AND**
• Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
• Patient must be under the care of the same physician for at least 6 months; **OR**
• Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
• Patient must have had, prior to commencement of non-PBS subsidised treatment with this drug, a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
• Patient must have had blood eosinophil count greater than or equal to 300 cells per microlitre prior to commencement of non-PBS subsidised treatment with this drug, **AND**
• Patient must have had a duration of asthma of at least 1 year prior to commencement of non-PBS subsidised treatment with this drug, **AND**
• Patient must have failed to achieve adequate control with optimised asthma therapy prior to non-PBS subsidised treatment with this drug despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
• Patient must have demonstrated an adequate response following at least 24 weeks of treatment of non-PBS subsidised benralizumab for this condition, **AND**
• The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised omalizumab or mepolizumab.

**Population criteria:**
• Patient must be aged 12 years or older.

Optimised asthma therapy includes:
(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**
(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, prior to commencing non-PBS subsidised treatment with this drug, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

An adequate response to benralizumab treatment is defined as:
(a) a reduction in the Asthma Control Questionnaire (ACQ 5) score of at least 0.5 from baseline; **OR**
(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ 5 score from baseline.

A multidisciplinary severe asthma clinic team comprises of:
• A respiratory physician; and
• A pharmacist, nurse or asthma educator.

A review of the patient's records should be conducted to extract pre- and post-benralizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Parameters to establish response are:
(i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5; and/or
(ii) maintenance oral corticosteroid dose reduced by at least 25% from baseline and no deterioration in ACQ 5 score from baseline.

The assessment of the patient's response to the initial PBS-subsidised course of treatment under this restriction must be made at around 16 weeks after the first dose of PBS-subsidised treatment with this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The
same parameters used to establish response to non-PBS subsidised therapy with this drug should be used for the assessment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

Patients will be eligible to receive continuing courses of treatment with this drug of up to 24 weeks providing they continue to demonstrate an adequate response to treatment. A patient may qualify for PBS-subsidised treatment under this restriction once only.

A patient who fails to respond to a course of PBS-subsidised benralizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with benralizumab, omalizumab or mepolizumab within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of benralizumab sufficient for up to 24 weeks of therapy. The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Eosinophilic Asthma Grandfather PBS Authority Application - Supporting Information Form, which includes the following:

(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and

(ii) details of pre- and post-benralizumab data on symptoms, quality of life, medication doses, severe exacerbation/s and hospitalisations, and

(c) a copy of the pre-benralizumab eosinophil pathology report; and

(d) a completed Asthma Control Questionnaire (ACQ 5) calculation sheet including the date of assessment of the patient's symptoms; or details of maintenance oral corticosteroid dose.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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

**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).

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**benralizumab 30 mg/mL injection, 1 mL syringe**

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**DEFERASIROX**

*Note* Pharmaceutical benefits that have the form deferasirox 125 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 90 mg film coated tablet are equivalent for the purposes of substitution.

*Note* Special Pricing Arrangements apply.

**Authority required**

Chronic iron overload

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

**Authority required**

Chronic iron overload

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

**deferasirox 125 mg dispersible tablet, 28**

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**DEFERASIROX**

**Note** Pharmaceutical benefits that have the form deferasirox 500 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 360 mg film coated tablet are equivalent for the purposes of substitution.

**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic iron overload
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

**Authority required**
Chronic iron overload
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

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11533B

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**DEFERASIROX**

**Note** Pharmaceutical benefits that have the form deferasirox 250 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 180 mg film coated tablet are equivalent for the purposes of substitution.

**Note** Special Pricing Arrangements apply.

**Authority required**
Chronic iron overload
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

**Authority required**
Chronic iron overload
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

deferasirox 250 mg dispersible tablet, 28
11240N

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**DEFERASIROX**

**Note** Pharmaceutical benefits that have the form deferasirox 250 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 180 mg film coated tablet are equivalent for the purposes of substitution.

**Note** Special Pricing Arrangements apply.

**Note** A patient's median life expectancy is determined by the severity of their underlying disease.

**Note** Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:
- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

**Note** Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:
- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).
Authority required
Chronic iron overload
Treatment Phase: Initial treatment

Clinical criteria:
- Patient must be red blood cell transfusion dependent, AND
- Patient must have a serum ferritin level of greater than 1000 microgram/L, AND
- Patient must have a malignant disorder of haemopoiesis, AND
- Patient must have a median life expectancy exceeding five years.

Deferasirox 250 mg dispersible tablet, 28

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Deferasirox

Note: Pharmaceutical benefits that have the form deferasirox 125 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 90 mg film coated tablet are equivalent for the purposes of substitution.

Note: Special Pricing Arrangements apply.

Note: A patient's median life expectancy is determined by the severity of their underlying disease.

Note: Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:
- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

Note: Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:
- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

Authority required
Chronic iron overload
Treatment Phase: Initial treatment

Clinical criteria:
- Patient must be red blood cell transfusion dependent, AND
- Patient must have a serum ferritin level of greater than 1000 microgram/L, AND
- Patient must have a malignant disorder of haemopoiesis, AND
- Patient must have a median life expectancy exceeding five years.

Deferasirox 125 mg dispersible tablet, 28

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Deferasirox 90 mg tablet, 30

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Deferasirox

Note: Pharmaceutical benefits that have the form deferasirox 125 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 90 mg film coated tablet are equivalent for the purposes of substitution.

Note: Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7384
Chronic iron overload
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must be transfusion dependent, AND
- Patient must not have a malignant disorder of erythropoiesis, AND
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.

Authority required (STREAMLINED)

7372
Chronic iron overload
Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must not be transfusion dependent, AND
- The condition must be thalassaemia, AND
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.
Highly Specialised Drugs Program (Public Hospital)

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

**125**

**Authority required (STREAMLINED)**

7395  
Chronic iron overload  
Treatment Phase: Continuing treatment  
**Clinical criteria:**  
- Patient must be red blood cell transfusion dependent, **AND**  
- Patient must have a malignant disorder of haemopoiesis, **AND**  
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.  
**Note** Interruption of treatment should be considered if serum ferritin levels fall consistently below 500 microgram/ml.

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**deferasirox 125 mg dispersible tablet, 28**

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**deferasirox 90 mg tablet, 30**

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### DEFERASIROX

**Note** Pharmaceutical benefits that have the form deferasirox 250 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 180 mg film coated tablet are equivalent for the purposes of substitution.

**Note** Special Pricing Arrangements apply.

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**deferasirox 250 mg dispersible tablet, 28**

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**deferasirox 180 mg tablet, 30**

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**DEFEASIROX**

**Note** Pharmaceutical benefits that have the form deferasirox 500 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 360 mg film coated tablet are equivalent for the purposes of substitution.

**Note** Special Pricing Arrangements apply.

**Note** A patient's median life expectancy is determined by the severity of their underlying disease.

**Note** Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:  
- low risk according to the International Prognostic Scoring System (IPSS); or  
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or  
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).
Note: Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:
- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

**Authority required**
Carcinoid syndrome
Treatment Phase: Initial treatment

**Clinical criteria:**
- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

### deferasirox 360 mg tablet, 30

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### DEFERASIROX

Note: Pharmaceutical benefits that have the form deferasirox 500 mg dispersible tablet and pharmaceutical benefits that have the form deferasirox 360 mg film coated tablet are equivalent for the purposes of substitution.

Note: Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**
7384
Chronic iron overload
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.

**Authority required (STREAMLINED)**
7372
Chronic iron overload
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia, **AND**
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.

**Authority required (STREAMLINED)**
7395
Chronic iron overload
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with this drug for this condition.

Note: Interruption of treatment should be considered if serum ferritin levels fall consistently below 500 microgram/ml.

### deferasirox 360 mg tablet, 30

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### deferasirox 500 mg dispersible tablet, 28

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### FILGRASTIM

**Authority required (STREAMLINED)**
7822
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
• Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

**Authority required (STREAMLINED)**

7843
Chemotherapy-induced neutropenia

**Clinical criteria:**
• Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
• Patient must have had a prior episode of febrile neutropenia; **OR**
• Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

**Authority required (STREAMLINED)**

6653
Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**
• The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required (STREAMLINED)**

6654
Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**
• The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required (STREAMLINED)**

6679
Assisting bone marrow transplantation

**Clinical criteria:**
• Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

**Authority required (STREAMLINED)**

6680
Assisting autologous peripheral blood progenitor cell transplantation

**Clinical criteria:**
• The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**Authority required (STREAMLINED)**

6621
Severe congenital neutropenia

**Clinical criteria:**
• Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
• Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

**Authority required (STREAMLINED)**

6640
Chronic cyclical neutropenia

**Clinical criteria:**
• Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
• Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; **OR**
• Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**Authority required (STREAMLINED)**

filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes

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filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes

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INFLIXIMAB

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, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy, 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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle. 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.

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.

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. 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 recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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

(iv) a patient wishes to re-commence 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 therapy 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 and golimumab and secukinumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

(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.

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. 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.

For second and subsequent continuing 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.

(3) Swapping therapy.

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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.

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) or continuing 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.

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. Where, 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.

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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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.

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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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: 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 psoriatic 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.

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; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

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.

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 must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

### INFLIXIMAB

**Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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.

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.

#### (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 recommencement of treatment after more than 5 years break in therapy); or

(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Re-commencement of treatment after a break in PBS-subsidised therapy); or

(iv) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years (Initial 2 - Change or Re-commencement of treatment after a break in PBS-subsidised therapy).

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

#### (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.

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.

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.

For second and subsequent continuing 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.

#### (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.
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 a 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 treatment application is
submitted within a treatment cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the
commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient
must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3
months at the time the ESR or CRP levels and the active joint counts are measured.
Note No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

8199
Severe psoriatic 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 psoriatic 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 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
application 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 under this restriction they will not be eligible to receive
further PBS-subsidised treatment with this drug in this treatment cycle.

### INFLIXIMAB

**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, secukinumab and ustekinumab for adult
patients with severe active psoriatic arthritis.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
Where the term ‘biological medicine’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol,
etanercept, golimumab, infliximab, secukinumab and ustekinumab only.

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 may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

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) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was issued in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

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.

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.

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.

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 recommencement of treatment after more than 5 years break in therapy); or
(ii) a patient wishes to re-commence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 1 - New patient or recommencement of treatment after more than 5 years break in therapy); or
(iii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (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
(iv) a patient wishes to re-commence 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 therapy 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 and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 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.

(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.

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.

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.

For second and subsequent continuing 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.

(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.

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 a 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 treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the
commencement of treatment with each initial treatment application must be 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 requalify for Initial 1 treatment with respect to both the indices of disease severity. A patient must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**

Severe psoriatic arthritis

**Treatment Phase: Initial 1 (new patient or recommencement of treatment after more than 5 years break in therapy)**

**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 prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition in the previous 5 years, AND
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be 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; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be conducted no later than 1 month from the date of completion of this initial course of treatment.

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 issued in this cycle and the date of the first application under a new cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Note** Biosimilar preferred prescribing policy

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** 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 the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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 2 (change or recommencement of treatment after a break in therapy 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 22 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:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

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).

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.
Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated.
This assessment, which will be used to determine eligibility for the first continuing treatment, must be conducted no later than 1 month from the date of completion of this initial course of treatment.
Where the most recent course of PBS-subsidised treatment with this drug was accessed under the first continuing or subsequent continuing treatment restriction, the patient must have been assessed for response.
Where a response assessment is not undertaken the patient will be deemed to have failed to respond to treatment with this drug.
If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.
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 issued in this cycle and the date of the first application under a new cycle.
At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.
Up to a maximum of 3 repeats will be authorised.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
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 or recommencement of treatment after more than 5 years break in therapy) restriction to complete 22 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 therapy of less than 5 years) restriction to complete 22 weeks treatment, AND
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

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

Note
Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required
Severe psoriatic 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 psoriatic arthritis.

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.

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; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

The application for first continuing treatment following an initial treatment course must be made following a minimum of 12 weeks of treatment with this drug. This assessment must be conducted no later than 4 weeks from the cessation of that treatment course.

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 issued in this cycle and the date of the first application under a new cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

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

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

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

Authority required
Severe psoriatic 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 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.

**Population criteria:**

- Patient must be aged 18 years or older.

**Note:** Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

<table>
<thead>
<tr>
<th>infliximab 100 mg injection, 1 vial</th>
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<tr>
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<tr>
<td>Max Qty Packs</td>
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**LANREOTIDE**

**Note:** No 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)**

8260
Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

**Clinical criteria:**
- The condition must be unresectable locally advanced disease or metastatic disease, AND
- The condition must be World Health Organisation (WHO) grade 1 or 2, AND
- The treatment must be as monotherapy.

**Population criteria:**
- Patient must be aged 18 years or older.
- WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (percentage) of less than or equal to 2.
- WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.
- Lanreotide is not PBS-subsidised for use in combination with everolimus or sunitinib for this condition.

<table>
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<tr>
<th>lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe</th>
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**LENOGRASTIM**

**Authority required (STREAMLINED)**

6522
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving standard dose adjuvant chemotherapy for breast cancer, AND
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), AND
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

6532
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving first-line chemotherapy for Hodgkin disease, AND
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), AND
- The treatment must be used in a patient for whom there is a clinical justification for wishing to continue chemotherapy with the same drug combination, dosage and treatment schedule, AND
- Patient must be anticipated to have a good response to treatment providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

6507
Chemotherapy-induced neutropenia

**Clinical criteria:**
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia.

**Authority required (STREAMLINED)**

6523
Chemotherapy-induced neutropenia

Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours.
Authority required (STREAMLINED)

6535
Chemotherapy-induced neutropenia
Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease.
Authority required (STREAMLINED)

6502
Chemotherapy-induced neutropenia
Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in an infant or child with central nervous system tumours.
Authority required (STREAMLINED)

6644
Chemotherapy-induced neutropenia
Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma.
Authority required (STREAMLINED)

6682
Chemotherapy-induced neutropenia
Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma.
Authority required (STREAMLINED)

6634
Chemotherapy-induced neutropenia
Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma.
Authority required (STREAMLINED)

6673
Chemotherapy-induced neutropenia
Clinical criteria:
- Patient must be receiving treatment with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade).
Authority required (STREAMLINED)

6654
Mobilisation of peripheral blood progenitor cells
Clinical criteria:
- The treatment must be in a normal volunteer for use in allogeneic transplantation.
Authority required (STREAMLINED)

6657
Assisting peripheral blood progenitor cell or bone marrow transplantation
Clinical criteria:
- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

lenograstim 13.4 million units (105 microgram) injection, 1 vial

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LENORASTIM 33.6 million units (263 microgram) injection, 1 vial

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### MEPOLIZUMAB

**Note** TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA

Patients are eligible to commence a 'mepolizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, a 'benralizumab treatment cycle' or an 'omalizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with benralizumab, mepolizumab or omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

1. **How to prescribe PBS-subsidised mepolizumab therapy:**
   (a) **Initial treatment:** Applications for initial treatment should be made where:
       i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or
       ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or
       iii) A patient has received prior PBS-subsidised benralizumab or omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

   All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy for mepolizumab.

   (b) **Continuing treatment:**

   Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

2. **Baseline measurements to determine response:**

   The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

3. **Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:**

   A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial benralizumab or omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

**Note** No increase 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** If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

**Note** For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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**

Uncontrolled severe eosinophilic asthma

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised benralizumab or omalizumab.

**Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to mepolizumab treatment is defined as:

1. A reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,
MEPOLIZUMAB

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE EOSINOPHILIC ASTHMA

Patients are eligible to commence a ‘mepolizumab treatment cycle’ (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to mepolizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised mepolizumab therapy before they are eligible to commence the next mepolizumab treatment cycle, or if eligible, a ‘benralizumab treatment cycle’ or an ‘omalizumab treatment cycle’. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised mepolizumab is stopped to the date of the first application for initial treatment with benralizumab, mepolizumab or omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised mepolizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

i) A patient has received no prior PBS-subsidised mepolizumab treatment and wishes to commence such therapy; or

ii) A patient wishes to recommence treatment with mepolizumab following a break in PBS-subsidised therapy of more than 6 months; or

iii) A patient has received prior PBS-subsidised benralizumab or omalizumab and wishes to commence treatment with mepolizumab after a treatment break of 6 months.

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy for mepolizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with mepolizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with mepolizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing mepolizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose, submitted with the Initial authority application for mepolizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent mepolizumab treatment cycle, or an initial benralizumab or omalizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

Note No increase 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 The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.
Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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

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).

Authority required
Uncontrolled severe eosinophilic asthma
Treatment Phase: Initial treatment

Treatment criteria:
- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:
- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, AND
- Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hypersensitivity defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than an 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, AND
- Patient must have a duration of asthma of at least 1 year, AND
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, AND
- Patient must have had blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months, AND
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, AND
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised benralizumab or omalizumab.

Population criteria:
- Patient must be aged 12 years or older.
- Optimised asthma therapy includes:
  - (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND
  - (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

The requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.
The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:
- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND
- (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.
  The Asthma Control Questionnaire (5 item version) assessment of the patient must be made at time of application for treatment (to establish baseline score) and again around 26 to 30 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.
This assessment at around 26 to 30 weeks, which will be used to determine eligibility for the first continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.
A patient who fails to respond to a course of PBS-subsidised mepolizumab for the treatment of uncontrolled severe eosinophilic asthma will not be eligible to receive further PBS-subsidised treatment with benralizumab, mepolizumab or omalizumab within 6 months of the date on which treatment was ceased.
At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of mepolizumab sufficient for up to 32 weeks of therapy.
A multidisciplinary severe asthma clinic team comprises of:
- A respiratory physician; and
- A pharmacist, nurse or asthma educator.
Mepolizumab must not be used concurrently with benralizumab or omalizumab, or within 6 months of each other. A patient is required to have ceased treatment with benralizumab or omalizumab for 6 months prior to initiating treatment with mepolizumab.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Eosinophilic Asthma Initial PBS Authority Application - Supporting Information Form, which includes the following:
(i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
(c) a copy of the eosinophil pathology report; and
(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient’s symptoms.

### Mepolizumab 100 mg injection, 1 vial

<table>
<thead>
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### MIDOSTAURIN

**Note** No increase 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 authority to prescribe may be made by phone 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**
Acute Myeloid Leukaemia
Treatment Phase: Maintenance therapy - Continuing treatment

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial maintenance or the initial maintenance grandfathering treatment restriction, **AND**
- Patient must not have developed disease progression while receiving PBS subsidised treatment with this drug for this condition, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant.
A maximum of 9 cycles will be authorised under this restriction in a lifetime.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle. If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:
- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.
A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

### Midostaurin 25 mg capsule, 112

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### MIDOSTAURIN

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

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

**Authority required**
Acute Myeloid Leukaemia
Treatment Phase: Maintenance therapy - Grandfathered treatment

**Clinical criteria:**
• Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2018, AND
• Patient must be receiving treatment with this drug for this condition at the time of application, AND
• Patient must not have developed disease progression while receiving treatment with this drug for this condition, AND
• Patient must have demonstrated complete remission after induction and consolidation chemotherapy in combination with midostaurin, AND
• Patient must not be undergoing or have undergone a stem cell transplant, AND
• The condition must have been internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition.

A maximum of 2 cycles will be authorised under this restriction in a lifetime.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the maintenance therapy continuing treatment criteria.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:
• Leukaemic cells in the CSF;
• Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
• Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
• Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The authority application must be made in writing and must include:
(1) a completed authority prescription form;
(2) a completed Acute myeloid leukaemia PBS Authority Application - Supporting Information Form; and
(3) confirmation that the patient is not undergoing or has not undergone a stem cell transplant; and
(4) confirmation that the patient does not have progressive disease; and
(5) a copy of a recent bone marrow biopsy report demonstrating that the patient is in complete remission; and
(6) a copy of the pathology test demonstrating that the condition was FMS tyrosine kinase 3 (FLT3) (ITD or TKD) mutation positive prior to commencing midostaurin.

midostaurin 25 mg capsule, 112

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**MIDOSTAURIN**

**Note** No increase 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.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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**

Acute Myeloid Leukaemia
Treatment Phase: Maintenance therapy - Initial treatment

**Clinical criteria:**
• Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
• Patient must not have developed disease progression while receiving PBS subsidised treatment with this drug for this condition, AND
• Patient must have demonstrated complete remission after induction and consolidation chemotherapy in combination with midostaurin, AND
• Patient must not be undergoing or have undergone a stem cell transplant, AND
• The condition must have been internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition.

A maximum of 3 cycles will be authorised under this restriction in a lifetime.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:
• Leukaemic cells in the CSF;
• Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
• Greater than 5% blasts in the marrow not attributable to bone marrow regeneration or another cause;
• Extramedullary leukaemia.
A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The authority application must be made in writing and include:

1. a completed authority prescription form;
2. a completed Acute myeloid leukaemia PBS Authority Application - Supporting Information Form; and
3. confirmation that the patient is not undergoing or has not undergone a stem cell transplant; and
4. confirmation that the patient does not have progressive disease; and
5. a copy of a recent bone marrow biopsy report demonstrating that the patient is in complete remission; and
6. a copy of the pathology test demonstrating that the condition was FMS tyrosine kinase 3 (FLT3) (ITD or TKD) mutation positive prior to commencing midostaurin.

### MIDOSTAURIN

**Note**
No increase 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 authority to prescribe may be made by phone 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

**Acute Myeloid Leukaemia**

**Clinical criteria:**

• Patient must not have received prior chemotherapy as induction therapy for this condition; OR
• The treatment must be for consolidation treatment following induction treatment with midostaurin in combination with chemotherapy, **AND**
• The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition, **AND**
• The condition must not be acute promyelocytic leukaemia, **AND**
• The treatment must be in combination with standard intensive remission induction or consolidation chemotherapy for this condition.

A maximum of 6 cycles will be authorised under this restriction in a lifetime.

Standard intensive remission induction combination chemotherapy must include cytarabine and an anthracycline. The FLT3 ITD or TKD mutation test result and date of testing must be provided at the time of application.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

• Leukaemic cells in the CSF;
• Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
• Greater than 5% blasts in the marrow not attributable to bone marrow regeneration or another cause;
• Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

### OCTREOTIDE

#### Authority required (STREAMLINED)

**8161**

**Acromegaly**

**Clinical criteria:**

• The condition must be controlled with octreotide immediate release injections, **AND**
• The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
• The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
• The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.
In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

**Authority required (STREAMLINED)**

**5901**

**Functional carcinoid tumour**

**Clinical criteria:**
- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required (STREAMLINED)**

**5906**

**Vasoactive intestinal peptide secreting tumour (VIPoma)**

**Clinical criteria:**
- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

| **octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack** |
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
| 10543X | 2 | 5 | .. | *2613.72 | Sandostatin LAR [NV] |

| **octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack** |
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
| 10533J | 2 | 5 | .. | *3479.62 | Sandostatin LAR [NV] |

| **octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack** |
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
| 10550G | 2 | 5 | .. | *4354.92 | Sandostatin LAR [NV] |

**OCTREOTIDE**

**Authority required (STREAMLINED)**

**8165**

**Acromegaly**

**Clinical criteria:**
- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; **OR**
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; **OR**
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, **AND**
- The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

**Authority required (STREAMLINED)**

**6390**

**Functional carcinoid tumour**

**Clinical criteria:**
- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required (STREAMLINED)**

**6369**

**Vasoactive intestinal peptide secreting tumour (VIPoma)**
Clinical criteria:

- The condition must be causing intractable symptoms, AND
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, AND
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, AND
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**OMALIZUMAB**

**Note** TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an ‘omalizumab treatment cycle’ (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next omalizumab treatment cycle or, if eligible, a 'benralizumab treatment cycle' or a 'mepolizumab treatment cycle'. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab is stopped to the date of the first application for initial treatment with benralizumab, omalizumab or mepolizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy:

(a) Initial treatment:

Applications for initial treatment should be made where:

i) A patient has received no prior PBS-subsidised omalizumab treatment and wishes to commence such therapy; or

ii) A patient wishes to recommence treatment with omalizumab following a break in PBS-subsidised therapy of at least 6 months; or

iii) A patient has received prior PBS-subsidised benralizumab or mepolizumab and wishes to commence treatment with omalizumab after a treatment break of at least 6 months.

All applications for initial treatment will be limited to provide for a maximum of up to 28 weeks of therapy of omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for omalizumab. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent omalizumab treatment cycle, or an initial benralizumab or mepolizumab treatment cycle, following a break in PBS-subsidised therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Special Pricing Arrangements apply.
• Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:
• Patient must be under the care of the same physician for at least 6 months; OR
• Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
• Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, **AND**
• Patient must have a duration of asthma of at least 1 year, **AND**
• Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 1 or more occasions in the previous 12 months, **AND**
• Patient must have past or current evidence of atopy, documented by skin prick testing or RAST, **AND**
• Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, **AND**
• Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
• Patient must not receive more than 28 weeks of treatment under this restriction, **AND**
• The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised benralizumab or mepolizumab.

Population criteria:
• Patient must be aged 12 years or older.

Optimised asthma therapy includes:
• (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**
• (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment must be no more than 12 months old at the time of application. The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:
• (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
• (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with benralizumab, omalizumab or mepolizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

A multidisciplinary severe asthma clinic team comprises of:
• A respiratory physician; and
• A pharmacist, nurse or asthma educator.

Omalizumab must not be used concurrently with benralizumab or mepolizumab, or within 6 months of each other. A patient is required to have ceased treatment with benralizumab or mepolizumab for 6 months prior to initiating treatment with omalizumab.

The authority application must be made in writing and must include:
• (a) a completed authority prescription form; and
• (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form, which includes the following:
  - (i) details of prior optimised asthma drug therapy (date of commencement and duration of therapy); and
  - (ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
• (c) the IgE pathology report; and
(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

**Note** The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270700 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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

**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).

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have a documented history of severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with, or within 6 months of treatment with, PBS-subsidised benralizumab or mepolizumab.

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, **OR**
(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline, **OR**
(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate must be made at around 18 to 22 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for up to 24 weeks of therapy. The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and
(b) a completed Severe Allergic Asthma PBS Authority Application and Supporting Information Form which includes details of maintenance oral corticosteroid dose; or
(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms and is endorsed with the signature of the prescriber, for patients transitioned from the paediatric to the adolescent/adult restrictions an exacerbation calculation sheet may be submitted.

**Note** If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

**Note** For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270700 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available
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).

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial and continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment; OR
- 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 28 weeks treatment available under the Initial restriction or up to 24 weeks treatment available under the Continuing restriction.

Note: Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment under the initial restriction or 24 weeks of treatment under the continuing restriction 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).

omalizumab 150 mg/mL injection, 1 mL syringe

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omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

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Highly Specialised Drugs Program (Community Access)

- **Dolutegravir + Rilpivirine**
  
  **Authority required (STREAMLINED)**

  **8214**
  
  HIV infection
  
  Treatment Phase: Initial treatment
  
  **Clinical criteria:**
  
  - Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months, **AND**
  
  - The treatment must be the sole PBS-subsidised therapy for this condition.

  **Authority required (STREAMLINED)**

  **8226**
  
  HIV infection
  
  Treatment Phase: Continuing treatment
  
  **Clinical criteria:**
  
  - Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
  
  - The treatment must be the sole PBS-subsidised therapy for this condition.

  **Dolutegravir 50 mg + Rilpivirine 25 mg tablet, 30**

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- **Octreotide**

  **Authority required (STREAMLINED)**

  **8197**
  
  Acromegaly
  
  **Clinical criteria:**
  
  - Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
  
  - The condition must be controlled with octreotide immediate release injections, **AND**
  
  - The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
  
  - The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
  
  - The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.

  In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

  **Authority required (STREAMLINED)**

  **8208**
  
  Functional carcinoid tumour
  
  **Clinical criteria:**
  
  - Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
  
  - Patient must have achieved symptom control on octreotide immediate release injections, **AND**
  
  - The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

  Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

  **Authority required (STREAMLINED)**

  **8198**
  
  Vasoactive intestinal peptide secreting tumour (VIPoma)
  
  **Clinical criteria:**
  
  - Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
  
  - Patient must have achieved symptom control on octreotide immediate release injections, **AND**
• The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

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octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

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octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

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Growth Hormone Program

- **SOMATROPIN**

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

  Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on 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

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

### Authority required

Severe growth hormone deficiency

**Treatment Phase:** Initial treatment

**Treatment criteria:**
- Must be treated by an endocrinologist.

**Clinical criteria:**
- Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; OR
- Patient must have adult onset growth hormone deficiency secondary to organic hypothalamic or pituitary disease, **AND**
- Patient must have an insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; OR
- Patient must have an arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; OR
- Patient must have a glucagon provocation test with maximum serum GH less than 3 micrograms per litre, **AND**
- Patient must have a quality of life (QoL) score on the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA) instrument of 16 or greater.

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

  Grandfathered patient who has previously received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2018 must have met all the initial restriction criteria prior to initiating non-PBS subsidised treatment. Additional information of a baseline serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks prior to initiating non-PBS subsidised treatment with this drug for this condition; and QoL score on the QoL-AGHDA instrument of 16 or greater, of less than 12 weeks prior to initiating non-PBS-subsidised treatment with this drug for this condition must be provided 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.

  The authority application must be in writing and must include:
  1. A completed authority prescription form; **AND**
  2. A completed Severe Growth Hormone Deficiency supporting information form; **AND**
  3. Confirmation of childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; **OR**
  4. Confirmation of adult onset growth hormone deficiency due to organic hypothalamic or pituitary disease; **AND**
  5. Results of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender; **AND**
  6. A baseline serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks old at the time of application; **AND**
  7. The patient's QoL score on the QoL-AGHDA instrument, including the date of testing, of less than 12 weeks old at the time of application.

### Authority required

Severe growth hormone deficiency

**Treatment Phase:** Continuing treatment

**Treatment criteria:**
- Must be treated by an endocrinologist or in consultation with an endocrinologist.

**Clinical criteria:**
• Patient must have previously received PBS-subsidised therapy with this drug for this condition at the age of 18 years or older, AND
• Patient must maintain IGF-1 levels within the normal range for age and sex, AND
• Patient must maintain a quality of life (QoL) score on the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA) instrument with a reduction of more than 7 points from baseline.

**Population criteria:**
• Patient must be aged 18 years or older.
The authority application must be in writing and must include:
1. A completed authority prescription form; AND
2. A completed Severe Growth Hormone Deficiency supporting information form; AND
3. A serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks old at the time of application; AND
4. The patient's QoL score on the QoL-AGHDA instrument, including the date of testing, of less than 12 weeks old at the time of application.

**SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1**

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**SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1**

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**somatropin 12 mg injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack**

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