Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 April 2018
Fees, Patient Contributions and Safety Net Thresholds

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

Dispensing Fees:

- Ready-prepared: $7.15
- Dangerous drug fee: $3.01
- Extemporarily-prepared: $9.19
- Allowable additional patient charge*: $4.45

Additional Fees (for safety net prices):

- Ready-prepared: $1.21
- Extemporarily-prepared: $1.57

Patient Co-payments:

- General: $39.50
- Concessional: $6.40

Safety Net Thresholds:

- General: $1521.80
- Concessional: $384.00

Safety Net Card Issue Fee: $9.91

* 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 April 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

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3496B</td>
<td>Butamol 2.5, QA – SALBUTAMOL</td>
<td>salbutamol 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules</td>
</tr>
<tr>
<td>3497C</td>
<td>Butamol 5, QA – SALBUTAMOL</td>
<td>salbutamol 5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules</td>
</tr>
</tbody>
</table>

#### Advance Notices

**1 August 2018**

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10244E</td>
<td>MassBiologics tetanus and diphtheria toxoids adsorbed, CS – DIPHTHERIA TOXOID + TETANUS TOXOID, diphtheria toxoid 2 Lf/0.5 mL + tetanus toxoid 2 Lf/0.5 mL injection, 10 x 0.5 mL vials</td>
<td></td>
</tr>
</tbody>
</table>

### General Pharmaceutical Benefits

#### Additions

<table>
<thead>
<tr>
<th>Code</th>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11273H</td>
<td>BUDERONIDE + FORMOTEROL (EFORMOTEROL)</td>
<td>budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations (DuoResp Spiromax)</td>
</tr>
<tr>
<td>11318Q</td>
<td>CERTOLIZUMAB PEGOL</td>
<td>certolizumab pegol 200 mg/mL injection, 2 x 1 mL injection devices (Cimzia)</td>
</tr>
<tr>
<td>11319R</td>
<td>CERTOLIZUMAB PEGOL</td>
<td>certolizumab pegol 200 mg/mL injection, 2 x 1 mL injection devices (Cimzia)</td>
</tr>
<tr>
<td>11320T</td>
<td>CERTOLIZUMAB PEGOL</td>
<td>certolizumab pegol 200 mg/mL injection, 2 x 1 mL injection devices (Cimzia)</td>
</tr>
<tr>
<td>11321W</td>
<td>CERTOLIZUMAB PEGOL</td>
<td>certolizumab pegol 200 mg/mL injection, 2 x 1 mL injection devices (Cimzia)</td>
</tr>
<tr>
<td>11322X</td>
<td>CERTOLIZUMAB PEGOL</td>
<td>certolizumab pegol 200 mg/mL injection, 2 x 1 mL injection devices (Cimzia)</td>
</tr>
<tr>
<td>11323Y</td>
<td>CERTOLIZUMAB PEGOL</td>
<td>certolizumab pegol 200 mg/mL injection, 2 x 1 mL injection devices (Cimzia)</td>
</tr>
<tr>
<td>11324B</td>
<td>CERTOLIZUMAB PEGOL</td>
<td>certolizumab pegol 200 mg/mL injection, 2 x 1 mL injection devices (Cimzia)</td>
</tr>
<tr>
<td>11325C</td>
<td>CERTOLIZUMAB PEGOL</td>
<td>certolizumab pegol 200 mg/mL injection, 2 x 1 mL injection devices (Cimzia)</td>
</tr>
<tr>
<td>11326D</td>
<td>CERTOLIZUMAB PEGOL</td>
<td>certolizumab pegol 200 mg/mL injection, 2 x 1 mL injection devices (Cimzia)</td>
</tr>
<tr>
<td>11291G</td>
<td>DAPAGLIFLOZIN</td>
<td>dapagliflozin 10 mg tablet, 28 (Forxiga)</td>
</tr>
<tr>
<td>11300R</td>
<td>DAPAGLIFLOZIN + METFORMIN</td>
<td>dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56 (Xigduo XR 5/1000)</td>
</tr>
<tr>
<td>11270E</td>
<td>DAPAGLIFLOZIN + METFORMIN</td>
<td>dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28 (Xigduo XR 10/500)</td>
</tr>
<tr>
<td>11317P</td>
<td>DEXAMETHASONE</td>
<td>dexamethasone 700 microgram implant, 1 (Ozurdex)</td>
</tr>
<tr>
<td>11314L</td>
<td>EMPAGLIFLOZIN</td>
<td>empagliflozin 10 mg tablet, 30 (Jardiance)</td>
</tr>
</tbody>
</table>
EMPAGLIFLOZIN, empagliflozin 25 mg tablet, 30 (Jardiance)

EMPAGLIFLOZIN + LINAGLIPTIN, empagliflozin 10 mg + linagliptin 5 mg tablet, 30 (Glyxambi)

EMPAGLIFLOZIN + LINAGLIPTIN, empagliflozin 10 mg + linagliptin 5 mg tablet, 30 (Glyxambi)

EMPAGLIFLOZIN + LINAGLIPTIN, empagliflozin 25 mg + linagliptin 5 mg tablet, 30 (Glyxambi)

EMPAGLIFLOZIN + LINAGLIPTIN, empagliflozin 25 mg + linagliptin 5 mg tablet, 30 (Glyxambi)

GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS, glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent bar, 14 x 81 g (Tylectin Complete)

GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS, glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g of protein equivalent powder for oral liquid, 60 x 32 g sachets (PKU Build 10)

GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS, glycomacropeptide and essential amino acids with vitamins and minerals containing 20 g of protein equivalent powder for oral liquid, 30 x 32 g sachets (PKU Build 20)

INSULIN GLARGINE, insulin glargine 300 units/mL injection, 5 x 1.5 mL injection devices (Toujeo Solostar)

INSULIN GLARGINE, insulin glargine 300 units/mL injection, 3 x 1.5 mL injection devices (Toujeo Solostar)

LINAGLIPTIN, linagliptin 5 mg tablet, 30 (Trajenta)

LINAGLIPTIN + METFORMIN, linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60 (Trajentamet)

LINAGLIPTIN + METFORMIN, linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60 (Trajentamet)

LINAGLIPTIN + METFORMIN, linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60 (Trajentamet)

METHOTREXATE, methotrexate 7.5 mg/0.15 mL injection, 0.15 mL syringe (Trexject)

METHOTREXATE, methotrexate 10 mg/0.2 mL injection, 0.2 mL syringe (Trexject)

METHOTREXATE, methotrexate 15 mg/0.3 mL injection, 0.3 mL syringe (Trexject)

METHOTREXATE, methotrexate 20 mg/0.4 mL injection, 0.4 mL syringe (Trexject)

METHOTREXATE, methotrexate 25 mg/0.5 mL injection, 0.5 mL syringe (Trexject)

SAXAGLIPTIN, saxagliptin 2.5 mg tablet, 28 (Onglyza)

SAXAGLIPTIN, saxagliptin 5 mg tablet, 28 (Onglyza)

SAXAGLIPTIN + DAPAGLIFLOZIN, saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28 (Qtern 5/10)

SAXAGLIPTIN + DAPAGLIFLOZIN, saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28 (Qtern 5/10)

SAXAGLIPTIN + METFORMIN, saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56 (Kombiglyze XR 2.5/1000)

SAXAGLIPTIN + METFORMIN, saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28 (Kombiglyze XR 5/500)

SAXAGLIPTIN + METFORMIN, saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28 (Kombiglyze XR 5/1000)

SONIDEGIB, sonidegib 200 mg capsule, 30 (Odomzo)

TENOFOVIR + EMTRICITABINE, tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30 (Tenofovir EMT GH)

VERTEPORFIN, verteporfin 15 mg injection, 1 vial (Visudyne)

Addition – Brand

Cyproterone 50, AL – CYPROTERONE, cyproterone acetate 50 mg tablet, 20

Cyproterone 50, AL – CYPROTERONE, cyproterone acetate 50 mg tablet, 50

Duloxetine Sandoz 30, SZ – DULOXETINE, duloxetine 30 mg enteric capsule, 28

Duloxetine Sandoz 60, SZ – DULOXETINE, duloxetine 60 mg enteric capsule, 28

Gastro-Stop, AS – LOPERAMIDE, loperamide hydrochloride 2 mg capsule, 12
1571Q Gastro-Stop, AS – LOPERAMIDE, loperamide hydrochloride 2 mg capsule, 12
2161R Pharmacor Olmesartan HCTZ 20/12.5, CR – OLMESARTAN MEDOXOMIL + HYDROCHLOROTHIAZIDE, olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30
2166B Pharmacor Olmesartan HCTZ 40/12.5, CR – OLMESARTAN MEDOXOMIL + HYDROCHLOROTHIAZIDE, olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30
2170F Pharmacor Olmesartan HCTZ 40/25, CR – OLMESARTAN MEDOXOMIL + HYDROCHLOROTHIAZIDE, olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30
1969P ACQUIN, RF – QUINAPRIL, quinapril 10 mg tablet, 30
10538P Rivastigmelon Patch 15, AF – RIVASTIGMINE, rivastigmine 13.3 mg/24 hours patch, 30
10541T Rivastigmelon Patch 15, AF – RIVASTIGMINE, rivastigmine 13.3 mg/24 hours patch, 30
5442K TOBRAMYCIN SUN, RA – TOBRAMYCIN, tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules

Addition – Equivalence Indicator
8625Y Symbicort Turbuhaler 200/6, AP – BUDESONIDE + FORMOTEROL (EFORMOTEROL), budesonide 200 microgram/actuation + formoterol (efformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations
8750M Symbicort Turbuhaler 400/12, AP – BUDESONIDE + FORMOTEROL (EFORMOTEROL), budesonide 400 microgram/actuation + formoterol (efformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 120 actuations

Addition – Note
8625Y BUDESONIDE + FORMOTEROL (EFORMOTEROL), budesonide 200 microgram/actuation + formoterol (efformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations (Symbicort Turbuhaler 200/6)
8750M BUDESONIDE + FORMOTEROL (EFORMOTEROL), budesonide 400 microgram/actuation + formoterol (efformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 120 actuations (Symbicort Turbuhaler 400/12)

Addition – Restriction
10510E DAPAGLIFLOZIN + METFORMIN, dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56 (Xigduo XR 5/1000)
10516L DAPAGLIFLOZIN + METFORMIN, dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28 (Xigduo XR 10/500)
10515K DAPAGLIFLOZIN + METFORMIN, dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28 (Xigduo XR 10/1000)
10627H EMPAGLIFLOZIN + METFORMIN, empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 (Jardiamet 5 mg/1000 mg)
10649L EMPAGLIFLOZIN + METFORMIN, empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 (Jardiamet 5 mg/1000 mg)
10626G EMPAGLIFLOZIN + METFORMIN, empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 (Jardiamet 5 mg/500 mg)
10650M EMPAGLIFLOZIN + METFORMIN, empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 (Jardiamet 5 mg/500 mg)
10640B EMPAGLIFLOZIN + METFORMIN, empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 (Jardiamet 12.5 mg/1000 mg)
10677Y EMPAGLIFLOZIN + METFORMIN, empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 (Jardiamet 12.5 mg/1000 mg)
10633P EMPAGLIFLOZIN + METFORMIN, empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 (Jardiamet 12.5 mg/500 mg)
10639Y EMPAGLIFLOZIN + METFORMIN, empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 (Jardiamet 12.5 mg/500 mg)
3387G LINAGLIPTIN, linagliptin 5 mg tablet, 30 (Trajenta)
10038H LINAGLIPTIN + METFORMIN, linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60 (Trajentamet)
<table>
<thead>
<tr>
<th>Item</th>
<th>Brand</th>
<th>Description</th>
<th>Quantity</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>10045Q</td>
<td>LINAGLIPTIN + METFORMIN</td>
<td>linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60 (Trajentamet)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10044P</td>
<td>LINAGLIPTIN + METFORMIN</td>
<td>linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60 (Trajentamet)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10128C</td>
<td>SAXAGLIPTIN</td>
<td>saxagliptin 2.5 mg tablet, 28 (Onglyza)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8983T</td>
<td>SAXAGLIPTIN</td>
<td>saxagliptin 5 mg tablet, 28</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10048W</td>
<td>SAXAGLIPTIN + METFORMIN</td>
<td>saxagliptin 2.5 mg + metformin hydrochloride modified release tablet, 56 (Kombiglyze XR 2.5/1000)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10055F</td>
<td>SAXAGLIPTIN + METFORMIN</td>
<td>saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28 (Kombiglyze XR 5/500)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10051B</td>
<td>SAXAGLIPTIN + METFORMIN</td>
<td>saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28 (Kombiglyze XR 5/1000)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3415R</td>
<td>VILDAGLIPTIN</td>
<td>vildagliptin 50 mg tablet, 60 (Galvus)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5474D</td>
<td>VILDAGLIPTIN + METFORMIN</td>
<td>vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60 (Galvumet 50/500)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5475E</td>
<td>VILDAGLIPTIN + METFORMIN</td>
<td>vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60 (Galvumet 50/850)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5476F</td>
<td>VILDAGLIPTIN + METFORMIN</td>
<td>vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60 (Galvumet 50/1000)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Deletions

<table>
<thead>
<tr>
<th>Deletion</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>218SB</td>
<td>TRIFLUOPERAZINE, trifluoperazine</td>
</tr>
<tr>
<td>2386N</td>
<td>TRIFLUOPERAZINE, trifluoperazine</td>
</tr>
<tr>
<td>2186C</td>
<td>TRIFLUOPERAZINE, trifluoperazine</td>
</tr>
</tbody>
</table>

Deletion – Brand

<table>
<thead>
<tr>
<th>Item Description</th>
<th>From</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clopidogrel RXB, RA – CLOPIDOGERL</td>
<td>8358X</td>
</tr>
<tr>
<td>Pharmacor Duloxetine 30, CR – DULOXETINE</td>
<td>9155W</td>
</tr>
<tr>
<td>Pharmacor Duloxetine 60, CR – DULOXETINE</td>
<td>9156X</td>
</tr>
<tr>
<td>Frusemide RXB, RA – FUROSEMIDE (FUROSEMIDE), furosemide</td>
<td>2414C</td>
</tr>
<tr>
<td>Frusemide RXB, RA – FUROSEMIDE (FUROSEMIDE), furosemide</td>
<td>2412Y</td>
</tr>
<tr>
<td>Chem mart Gliclazide MR, CH – GLICLAZIDE</td>
<td>8535F</td>
</tr>
<tr>
<td>Terry White Chemists Gliclazide MR, TW – GLICLAZIDE</td>
<td>8535F</td>
</tr>
<tr>
<td>Irbesartan RBX, RA – IRBESARTAN</td>
<td>8247C</td>
</tr>
<tr>
<td>Irbesartan RBX, RA – IRBESARTAN</td>
<td>8248D</td>
</tr>
<tr>
<td>Irbesartan/HCTZ RBX 150/12.5, RA – IRBESARTAN + HYDROCHLOROTHIAZIDE</td>
<td>8404H</td>
</tr>
<tr>
<td>Irbesartan/HCTZ RBX 300/25, RA – IRBESARTAN + HYDROCHLOROTHIAZIDE</td>
<td>2136K</td>
</tr>
<tr>
<td>Chem mart Ramipril, CH – RAMIPRIL</td>
<td>9120B</td>
</tr>
<tr>
<td>Terry White Chemists Ramipril, TW – RAMIPRIL</td>
<td>9120B</td>
</tr>
<tr>
<td>Butamol 2.5, QA – SALBUTAMOL</td>
<td>2000G</td>
</tr>
<tr>
<td>Butamol 5, QA – SALBUTAMOL</td>
<td>2001H</td>
</tr>
<tr>
<td>Ransim, RA – SIMVASTATIN</td>
<td>2012X</td>
</tr>
<tr>
<td>Ransim, RA – SIMVASTATIN</td>
<td>9243L</td>
</tr>
<tr>
<td>Ransim, RA – SIMVASTATIN</td>
<td>8173E</td>
</tr>
<tr>
<td>Ransim, RA – SIMVASTATIN</td>
<td>9244M</td>
</tr>
</tbody>
</table>

Deletion – Note

<table>
<thead>
<tr>
<th>Item Description</th>
<th>From</th>
</tr>
</thead>
<tbody>
<tr>
<td>VERTEPORFIN, vertoporfin</td>
<td>1349B</td>
</tr>
</tbody>
</table>

Alterations

<table>
<thead>
<tr>
<th>Alteration – Item Description</th>
<th>From</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEFUROXIME, CEFUROXIME AXETIL Powder for oral suspension</td>
<td>2002J</td>
</tr>
</tbody>
</table>

Schedule of Pharmaceutical Benefits – April 2018
To

CEFUROXIME, cefuroxime 125 mg/5 mL powder for oral liquid, 70 mL (Zinnat)

From

CEFUROXIME, CEFUROXIME AXETIL Powder for oral suspension 125 mg (base) per 5 mL, 70 mL, 1 (Zinnat)

To

CEFUROXIME, cefuroxime 125 mg/5 mL powder for oral liquid, 70 mL (Zinnat)

From

INTERFERON BETA-1A, interferon beta-1a 44 microgram/0.5 mL (12 million units) injection, 12 x 0.5 mL syringes (Rebif 44)

To

INTERFERON BETA-1A, interferon beta-1a 12 million units (44 microgram)/0.5 mL injection, 12 x 0.5 mL syringes (Rebif 44)

From

INTERFERON BETA-1A, interferon beta-1a 132 microgram/1.5 mL (12 million units) injection, 4 x 1.5 mL cartridges (Rebif 44)

To

INTERFERON BETA-1A, interferon beta-1a 12 million units (132 microgram)/1.5 mL injection, 4 x 1.5 mL cartridges (Rebif 44)

From

MYCOBACTERIUM BOVIS (BACILLUS CALMETTE AND GUERIN (BCG)) TICE STRAIN, Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Tice strain 500 million colony forming units injection, 3 vials (OncoTICE)

To

MYCOBACTERIUM BOVIS (BACILLUS CALMETTE AND GUERIN (BCG)) TICE STRAIN, Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Tice strain 500 million CFU injection, 3 vials (OncoTICE)

From

PARAFFIN, paraffin + retinol palmitate 0.0138% eye ointment, 5 g (VitA-POS)

To

PARAFFIN, retinol palmitate 0.0138% + paraffin eye ointment, 5 g (VitA-POS)

From

PARAFFIN, paraffin + retinol palmitate 0.0138% eye ointment, 5 g (VitA-POS)

To

PARAFFIN, retinol palmitate 0.0138% + paraffin eye ointment, 5 g (VitA-POS)

From

SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM, sorbitol 3.125 g/5 mL + sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL (Micolette)

To

CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL, sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 12 x 5 mL (Micolette)

Alteration – Note

10011X DAPAGLIFLOZIN, dapagliflozin 10 mg tablet, 28 (Forxiga)

10510E DAPAGLIFLOZIN + METFORMIN, dapagliflozin 5 mg + metformin hydrochloride 1 g modified release tablet, 56 (Xigduo XR 5/1000)

10516L DAPAGLIFLOZIN + METFORMIN, dapagliflozin 10 mg + metformin hydrochloride 500 mg modified release tablet, 28 (Xigduo XR 10/500)

10515K DAPAGLIFLOZIN + METFORMIN, dapagliflozin 10 mg + metformin hydrochloride 1 g modified release tablet, 28 (Xigduo XR 10/1000)

10206E EMPAGLIFLOZIN, empagliflozin 10 mg tablet, 30 (Jardiance)

10202Y EMPAGLIFLOZIN, empagliflozin 25 mg tablet, 30 (Jardiance)

10627H EMPAGLIFLOZIN + METFORMIN, empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 (Jardiamet 5 mg/1000 mg)

10649L EMPAGLIFLOZIN + METFORMIN, empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 (Jardiamet 5 mg/1000 mg)
10626G EMPAGLIFLOZIN + METFORMIN, empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 (Jardiamet 5 mg/500 mg)

10650M EMPAGLIFLOZIN + METFORMIN, empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 (Jardiamet 5 mg/500 mg)

10640B EMPAGLIFLOZIN + METFORMIN, empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 (Jardiamet 12.5 mg/1000 mg)

10677Y EMPAGLIFLOZIN + METFORMIN, empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60 (Jardiamet 12.5 mg/1000 mg)

10633P EMPAGLIFLOZIN + METFORMIN, empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 (Jardiamet 12.5 mg/500 mg)

10639Y EMPAGLIFLOZIN + METFORMIN, empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 (Jardiamet 12.5 mg/500 mg)

3387G LINAGLIPTIN, linagliptin 5 mg tablet, 30 (Trajenta)

10038H LINAGLIPTIN + METFORMIN, linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60 (Trajentamet)

10045Q LINAGLIPTIN + METFORMIN, linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60 (Trajentamet)

10044P LINAGLIPTIN + METFORMIN, linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60 (Trajentamet)

10128C SAXAGLIPTIN, saxagliptin 2.5 mg tablet, 28 (Onglyza)

8983T SAXAGLIPTIN, saxagliptin 5 mg tablet, 28 (Onglyza)

10048W SAXAGLIPTIN + METFORMIN, saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56 (Kombiglyze XR 2.5/1000)

10055F SAXAGLIPTIN + METFORMIN, saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28 (Kombiglyze XR 5/500)

10051B SAXAGLIPTIN + METFORMIN, saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28 (Kombiglyze XR 5/1000)

11070P VISMODEGIB, vismodegib 150 mg capsule, 28 (Erivedge)

Alteration – Restriction

10505X AFLIBERCEPT, aflibercept 4 mg/0.1 mL injection, 0.1 mL vial (Eylea)

2168D AFLIBERCEPT, aflibercept 4 mg/0.1 mL injection, 0.1 mL vial (Eylea)

10011X DAPAGLIFLOZIN, dapagliflozin 10 mg tablet, 28 (Forxiga)

10943Y DEXAMETHASONE, dexamethasone 700 microgram implant, 1 (Ozurdex)

10206E EMPAGLIFLOZIN, empagliflozin 10 mg tablet, 30 (Jardiance)

10202Y EMPAGLIFLOZIN, empagliflozin 25 mg tablet, 30 (Jardiance)

10138N RANIBIZUMAB, ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe (Lucentis)

10374B RANIBIZUMAB, ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe (Lucentis)

10373Y RANIBIZUMAB, ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial (Lucentis)

1382R RANIBIZUMAB, ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial (Lucentis)

1349B VERTEPORFIN, verteporfin 15 mg injection, 1 vial (Visudyne)

11070P VISMODEGIB, vismodegib 150 mg capsule, 28 (Erivedge)

Alteration – Manufacturer Code

5502N Poly Gel – CARBOMER-974, cariomer-974 0.3% eye gel, 30 x 500 mg unit doses  From NV To AQ

8514D Poly Gel – CARBOMER-974, cariomer-974 0.3% eye gel, 30 x 500 mg unit doses  From NV To AQ

5521N Bion Tears – DEXTRAN + HYPROMELLOSE, dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses  From NV To AQ

8299T Bion Tears – DEXTRAN + HYPROMELLOSE, dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses  From NV To AQ
Poly-Tears – DEXTRAN-70 + HYPROMELLOSE, dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

Tears Naturale – DEXTRAN-70 + HYPROMELLOSE, dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

Poly-Tears – DEXTRAN-70 + HYPROMELLOSE, dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

Tears Naturale – DEXTRAN-70 + HYPROMELLOSE, dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

Poly-Tears – DEXTRAN-70 + HYPROMELLOSE, dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

Tears Naturale – DEXTRAN-70 + HYPROMELLOSE, dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

Genteal – HYPROMELLOSE, HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1

In a Wink Moisturising – HYPROMELLOSE, HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1

Genteal – HYPROMELLOSE, HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1

Genteal gel – HYPROMELLOSE + CARBOMER-980, hypromellose 0.3% + carborner-980 0.2% eye gel, 10 g

HPMC PAA – HYPROMELLOSE + CARBOMER-980, hypromellose 0.3% + carborner-980 0.2% eye gel, 10 g

Genteal gel – HYPROMELLOSE + CARBOMER-980, hypromellose 0.3% + carborner-980 0.2% eye gel, 10 g

HPMC PAA – HYPROMELLOSE + CARBOMER-980, hypromellose 0.3% + carborner-980 0.2% eye gel, 10 g

Genteal gel – HYPROMELLOSE + CARBOMER-980, hypromellose 0.3% + carborner-980 0.2% eye gel, 10 g

Bondronat – IBANDRONATE, ibandronate 50 mg tablet, 28

Molaxole – MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE, macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets

Aurorix – MOCLOBEMIDE, moclobemide 150 mg tablet, 60

Aurorix 300 mg – MOCLOBEMIDE, moclobemide 300 mg tablet, 60

Sevikar 20/5 – OLMESARTAN MEDOXOMIL + AMLODIPINE, olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30

Sevikar 40/5 – OLMESARTAN MEDOXOMIL + AMLODIPINE, olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30

Sevikar 40/10 – OLMESARTAN MEDOXOMIL + AMLODIPINE, olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30

Poly Visc – PARAFFIN, paraffin 1 g/g eye ointment, 3.5 g

Poly Visc – PARAFFIN, paraffin 1 g/g eye ointment, 3.5 g

Poly Visc – PARAFFIN, paraffin 1 g/g eye ointment, 3.5 g

Poly Visc – PARAFFIN, paraffin 1 g/g eye ointment, 2 x 3.5 g
Advance Notices

1 May 2018
Deletion – Brand
9049G Caduet 5/10, PF – AMLODIPINE + ATORVASTATIN, amlodipine 5 mg + atorvastatin 10 mg tablet, 30
9050H Caduet 5/20, PF – AMLODIPINE + ATORVASTATIN, amlodipine 5 mg + atorvastatin 20 mg tablet, 30
1886G Ranmoxy, RA – AMOXICILLIN, amoxicillin 125 mg/5 mL powder for oral liquid, 100 mL
1887H Ranmoxy, RA – AMOXICILLIN, amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL
3393N Ranmoxy, RA – AMOXICILLIN, amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL
2742H Flutamide MYLAN, AF – FLUTAMIDE, flutamide 250 mg tablet, 30
8974H Actonel EC Combi D, UA – RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL, RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1
10551H MAXATAN, RW – RIZATRIPTAN, rizatriptan 10 mg orally disintegrating tablet, 2

1 June 2018
Deletion – Brand
2479L Donepezil generichealth, GQ – DONEPEZIL, donepezil hydrochloride 10 mg tablet, 28
2532G Donepezil generichealth, GQ – DONEPEZIL, donepezil hydrochloride 5 mg tablet, 28
8496E Donepezil generichealth, GQ – DONEPEZIL, donepezil hydrochloride 10 mg tablet, 28
8348J Intron A Redipen, MK – INTERFERON ALFA-2B, interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL
8476D Intron A Redipen, MK – INTERFERON ALFA-2B, interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL
8572E Intron A Redipen, MK – INTERFERON ALFA-2B, interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL
1024X Olanzapine generichealth 2.5, GQ – OLANZAPINE, olanzapine 2.5 mg tablet, 28

1 August 2018
Deletion – Brand
10261C MassBiologics tetanus and diphtheria toxoids adsorbed, CS – DIPHTHERIA TOXOID + TETANUS TOXOID, diphtheria toxoid 2 Lf/0.5 mL + tetanus toxoid 2 Lf/0.5 mL injection, 10 x 0.5 mL vials
Palliative Care

Alterations – Item Description

Alteration
From
5331N SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM, sorbitol 3.125 g/5 mL + sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL (Micolette)
To
5331N CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL, sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 12 x 5 mL (Micolette)

Alteration – Manufacturer Code

5389P Molaxole – MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE, macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Brand
6136Y GANCICLOVIR SXP, HN – GANCICLOVIR, ganciclovir 500 mg injection, 5 vials

Addition – Equivalence Indicator
6136Y Cymevene, RO – GANCICLOVIR, ganciclovir 500 mg injection, 5 vials

Alterations

Alteration – Manufacturer Code

9619G Bondronat – IBANDRONATE, ibandronate 6 mg/6 mL injection, 6 mL vial

Advance Notices

1 June 2018

Deletion – Brand
6218G Intron A, MK – INTERFERON ALFA-2B, interferon alfa-2b 18 million units/3 mL injection, 3 mL vial
6219H Intron A, MK – INTERFERON ALFA-2B, interferon alfa-2b 25 million units/2.5 mL injection, 2.5 mL vial
6246R Intron A, MK – INTERFERON ALFA-2B, interferon alfa-2b 10 million units/mL injection, 5 x 1 mL vials
6253D Intron A Redipen, MK – INTERFERON ALFA-2B, interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL
6254E Intron A Redipen, MK – INTERFERON ALFA-2B, interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL
6255F Intron A Redipen, MK – INTERFERON ALFA-2B, interferon alfa-2b 60 million units/1.2 mL injection, 1.2 mL

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Brand
5749N GANCICLOVIR SXP, HN – GANCICLOVIR, ganciclovir 500 mg injection, 5 vials

Addition – Equivalence Indicator
5749N Cymevene, RO – GANCICLOVIR, ganciclovir 500 mg injection, 5 vials

Alterations

Alteration – Manufacturer Code

5750P Bondronat – IBANDRONATE, ibandronate 6 mg/6 mL injection, 6 mL vial

Advance Notices

1 June 2018

Deletion – Brand
5763H Intron A Redipen, MK – INTERFERON ALFA-2B, interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL
5764J Intron A Redipen, MK – INTERFERON ALFA-2B, interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL
Highly Specialised Drugs Program (Community Access)

Additions

Addition – Item

11315M LANREOTIDE, lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe (Somatuline Autogel)
11316N LANREOTIDE, lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe (Somatuline Autogel)
11289E LANREOTIDE, lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe (Somatuline Autogel)

Addition – Brand

10357D Abacavir/Lamivudine Mylan, AF – ABACAVIR + LAMIVUDINE, abacavir 600 mg + lamivudine 300 mg tablet, 30

Advance Notices
1 June 2018

Deletion – Brand

10312R Zerit, BQ – STAVUDINE, stavudine 30 mg capsule, 60
10311T Zerit, BQ – STAVUDINE, stavudine 40 mg capsule, 60

Growth Hormone Program

Deletions

Deletion – Item

10441M SOMATROPIN, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge (Omnitrope)
10481P SOMATROPIN, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge (Omnitrope)
6311E SOMATROPIN, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge (Omnitrope)

Alterations

Alteration – Item Description

From 10456H SOMATROPIN, somatropin 1.8 units (600 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)
To 10456H SOMATROPIN, somatropin 600 microgram injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)

From 10477K SOMATROPIN, somatropin 1.8 units (600 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)
To 10477K SOMATROPIN, somatropin 600 microgram injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)

From 9628R SOMATROPIN, somatropin 1.8 units (600 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)
From 6313G SOMATROPIN, somatropin 2.4 units (800 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)
To 6314H SOMATROPIN, somatropin 3.6 units (1.2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)
<table>
<thead>
<tr>
<th>From</th>
<th>To</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>10488B</td>
<td>10488B</td>
<td>SOMATROPIN, somatropin 4.2 units (1.4 mg) injection [7] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)</td>
</tr>
<tr>
<td>6316K</td>
<td>6316K</td>
<td>SOMATROPIN, somatropin 1.4 mg injection [7] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)</td>
</tr>
<tr>
<td>10454F</td>
<td>10454F</td>
<td>SOMATROPIN, somatropin 4.8 units (1.6 mg) injection [7] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)</td>
</tr>
<tr>
<td>10498M</td>
<td>10498M</td>
<td>SOMATROPIN, somatropin 1.6 mg injection [7] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)</td>
</tr>
<tr>
<td>6317L</td>
<td>6317L</td>
<td>SOMATROPIN, somatropin 4.8 units (1.6 mg) injection [7] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)</td>
</tr>
<tr>
<td>10500P</td>
<td>10500P</td>
<td>SOMATROPIN, somatropin 5.4 units (1.8 mg) injection [7] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)</td>
</tr>
<tr>
<td>10501Q</td>
<td>10501Q</td>
<td>SOMATROPIN, somatropin 1.8 mg injection [7] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)</td>
</tr>
<tr>
<td>6318M</td>
<td>6318M</td>
<td>SOMATROPIN, somatropin 5.4 units (1.8 mg) injection [7] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)</td>
</tr>
<tr>
<td>10428W</td>
<td>10428W</td>
<td>SOMATROPIN, somatropin 6 units (2 mg) injection [7] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)</td>
</tr>
<tr>
<td>10472E</td>
<td>10472E</td>
<td>SOMATROPIN, somatropin 2 mg injection [7] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)</td>
</tr>
<tr>
<td>6319N</td>
<td>6319N</td>
<td>SOMATROPIN, somatropin 6 units (2 mg) injection [7] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)</td>
</tr>
</tbody>
</table>
To 6319N
SOMATROPIN, somatropin 2 mg injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)

From 10447W
SOMATROPIN, somatropin 12 units (4 mg) injection [1 vial] (&) inert substance diluent [1 vial], 1 pack (Zomacton)
To 10447W
SOMATROPIN, somatropin 4 mg injection [1 vial] (&) inert substance diluent [1 vial], 1 pack (Zomacton)

From 10452D
SOMATROPIN, somatropin 12 units (4 mg) injection [1 vial] (&) inert substance diluent [1 vial], 1 pack (Zomacton)
To 10452D
SOMATROPIN, somatropin 4 mg injection [1 vial] (&) inert substance diluent [1 vial], 1 pack (Zomacton)

From 6266T
SOMATROPIN, somatropin 12 units (4 mg) injection [1 vial] (&) inert substance diluent [1 vial], 1 pack (Zomacton)
To 6266T
SOMATROPIN, somatropin 4 mg injection [1 vial] (&) inert substance diluent [1 vial], 1 pack (Zomacton)

From 10440L
SOMATROPIN, somatropin 30 units (10 mg) injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack (Zomacton)
To 10440L
SOMATROPIN, somatropin 10 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack (Zomacton)

From 10455G
SOMATROPIN, somatropin 30 units (10 mg) injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack (Zomacton)
To 10455G
SOMATROPIN, somatropin 10 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack (Zomacton)

From 6310D
SOMATROPIN, somatropin 30 units (10 mg) injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack (Zomacton)
To 6310D
SOMATROPIN, somatropin 10 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack (Zomacton)

From 10444Q
SOMATROPIN, somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack (Genotropin)
To 10444Q
SOMATROPIN, somatropin 12 mg injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack (Genotropin)

From 10499N
SOMATROPIN, somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack (Genotropin)
To 10499N
SOMATROPIN, somatropin 12 mg injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack (Genotropin)

From 6312F
SOMATROPIN, somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack (Genotropin)
To 6312F
SOMATROPIN, somatropin 12 mg injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack (Genotropin)

From 10429X
SOMATROPIN, somatropin 18 units (6 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack (Humatrope)
To 10429X
SOMATROPIN, somatropin 6 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack (Humatrope)

From 10482Q
SOMATROPIN, somatropin 18 units (6 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack (Humatrope)
To 10482Q
SOMATROPIN, somatropin 6 mg injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack (Humatrope)

From 6169Q
SOMATROPIN, somatropin 18 units (6 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack (Humatrope)
<table>
<thead>
<tr>
<th>From</th>
<th>To</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>6169Q</td>
<td>SOMATROPIN, somatropin 6 mg injection [1 cartridge] (&amp;) inert substance diluent [3.15 mL syringe], 1 pack</td>
<td></td>
</tr>
<tr>
<td>10461N</td>
<td>SOMATROPIN, somatropin 36 units (12 mg) injection [1 cartridge] (&amp;) inert substance diluent [3.15 mL syringe], 1 pack</td>
<td></td>
</tr>
<tr>
<td>10461N</td>
<td>SOMATROPIN, somatropin 12 mg injection [1 cartridge] (&amp;) inert substance diluent [3.15 mL syringe], 1 pack</td>
<td></td>
</tr>
<tr>
<td>10487Y</td>
<td>SOMATROPIN, somatropin 36 units (12 mg) injection [1 cartridge] (&amp;) inert substance diluent [3.15 mL syringe], 1 pack</td>
<td></td>
</tr>
<tr>
<td>10487Y</td>
<td>SOMATROPIN, somatropin 12 mg injection [1 cartridge] (&amp;) inert substance diluent [3.15 mL syringe], 1 pack</td>
<td></td>
</tr>
<tr>
<td>6170R</td>
<td>SOMATROPIN, somatropin 36 units (12 mg) injection [1 cartridge] (&amp;) inert substance diluent [3.15 mL syringe], 1 pack</td>
<td></td>
</tr>
<tr>
<td>6170R</td>
<td>SOMATROPIN, somatropin 12 mg injection [1 cartridge] (&amp;) inert substance diluent [3.15 mL syringe], 1 pack</td>
<td></td>
</tr>
<tr>
<td>10476J</td>
<td>SOMATROPIN, somatropin 72 units (24 mg) injection [1 cartridge] (&amp;) inert substance diluent [3.15 mL syringe], 1 pack</td>
<td></td>
</tr>
<tr>
<td>10476J</td>
<td>SOMATROPIN, somatropin 24 mg injection [1 cartridge] (&amp;) inert substance diluent [3.15 mL syringe], 1 pack</td>
<td></td>
</tr>
<tr>
<td>10502R</td>
<td>SOMATROPIN, somatropin 72 units (24 mg) injection [1 cartridge] (&amp;) inert substance diluent [3.15 mL syringe], 1 pack</td>
<td></td>
</tr>
<tr>
<td>10502R</td>
<td>SOMATROPIN, somatropin 24 mg injection [1 cartridge] (&amp;) inert substance diluent [3.15 mL syringe], 1 pack</td>
<td></td>
</tr>
<tr>
<td>6345Y</td>
<td>SOMATROPIN, somatropin 72 units (24 mg) injection [1 cartridge] (&amp;) inert substance diluent [3.15 mL syringe], 1 pack</td>
<td></td>
</tr>
<tr>
<td>6345Y</td>
<td>SOMATROPIN, somatropin 24 mg injection [1 cartridge] (&amp;) inert substance diluent [3.15 mL syringe], 1 pack</td>
<td></td>
</tr>
<tr>
<td>10432C</td>
<td>SOMATROPIN, somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge (Norditropin FlexPro)</td>
<td></td>
</tr>
<tr>
<td>10432C</td>
<td>SOMATROPIN, somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge (Norditropin FlexPro)</td>
<td></td>
</tr>
<tr>
<td>10437H</td>
<td>SOMATROPIN, somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge (Norditropin SimpleXx)</td>
<td></td>
</tr>
<tr>
<td>10437H</td>
<td>SOMATROPIN, somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge (Norditropin SimpleXx)</td>
<td></td>
</tr>
<tr>
<td>10467X</td>
<td>SOMATROPIN, somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge (Norditropin FlexPro)</td>
<td></td>
</tr>
<tr>
<td>10467X</td>
<td>SOMATROPIN, somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge (Norditropin FlexPro)</td>
<td></td>
</tr>
<tr>
<td>10469B</td>
<td>SOMATROPIN, somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge (Norditropin SimpleXx)</td>
<td></td>
</tr>
<tr>
<td>10469B</td>
<td>SOMATROPIN, somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge (Norditropin SimpleXx)</td>
<td></td>
</tr>
<tr>
<td>10507B</td>
<td>SOMATROPIN, somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge (Omnitrope Surepal 5)</td>
<td></td>
</tr>
<tr>
<td>10507B</td>
<td>SOMATROPIN, somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge (Omnitrope Surepal 5)</td>
<td></td>
</tr>
<tr>
<td>10512G</td>
<td>SOMATROPIN, somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge (Omnitrope Surepal 5)</td>
<td></td>
</tr>
<tr>
<td>10512G</td>
<td>SOMATROPIN, somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge (Omnitrope Surepal 5)</td>
<td></td>
</tr>
<tr>
<td>From</td>
<td>To</td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td>-------------------</td>
<td></td>
</tr>
<tr>
<td>10518N SOMATROPIN</td>
<td>10518N SOMATROPIN</td>
<td></td>
</tr>
<tr>
<td>SOMATROPIN, somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge (Omnitrope Surepal 5)</td>
<td>SOMATROPIN, somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge (Omnitrope Surepal 5)</td>
<td></td>
</tr>
<tr>
<td>5818F SOMATROPIN</td>
<td>5818F SOMATROPIN</td>
<td></td>
</tr>
<tr>
<td>SOMATROPIN, somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge (Norditropin FlexPro)</td>
<td>SOMATROPIN, somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge (Norditropin FlexPro)</td>
<td></td>
</tr>
<tr>
<td>6295H SOMATROPIN</td>
<td>6295H SOMATROPIN</td>
<td></td>
</tr>
<tr>
<td>SOMATROPIN, somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge (Norditropin SimpleXx)</td>
<td>SOMATROPIN, somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge (Norditropin SimpleXx)</td>
<td></td>
</tr>
<tr>
<td>10458K SOMATROPIN</td>
<td>10458K SOMATROPIN</td>
<td></td>
</tr>
<tr>
<td>SOMATROPIN, somatropin 18 units (6 mg/1.03 mL) injection, 1.03 mL cartridge (Saizen)</td>
<td>SOMATROPIN, somatropin 6 mg/1.03 mL injection, 1.03 mL cartridge (Saizen)</td>
<td></td>
</tr>
<tr>
<td>10462P SOMATROPIN</td>
<td>10462P SOMATROPIN</td>
<td></td>
</tr>
<tr>
<td>SOMATROPIN, somatropin 18 units (6 mg/1.03 mL) injection, 1.03 mL cartridge (Saizen)</td>
<td>SOMATROPIN, somatropin 6 mg/1.03 mL injection, 1.03 mL cartridge (Saizen)</td>
<td></td>
</tr>
<tr>
<td>5822K SOMATROPIN</td>
<td>5822K SOMATROPIN</td>
<td></td>
</tr>
<tr>
<td>SOMATROPIN, somatropin 18 units (6 mg/1.03 mL) injection, 1.03 mL cartridge (Saizen)</td>
<td>SOMATROPIN, somatropin 6 mg/1.03 mL injection, 1.03 mL cartridge (Saizen)</td>
<td></td>
</tr>
<tr>
<td>10438J SOMATROPIN</td>
<td>10438J SOMATROPIN</td>
<td></td>
</tr>
<tr>
<td>SOMATROPIN, somatropin 30 units (10 mg/2 mL) injection, 2 mL cartridge (NutropinAq)</td>
<td>SOMATROPIN, somatropin 10 mg/2 mL injection, 2 mL cartridge (NutropinAq)</td>
<td></td>
</tr>
<tr>
<td>10439K SOMATROPIN</td>
<td>10439K SOMATROPIN</td>
<td></td>
</tr>
<tr>
<td>SOMATROPIN, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge (Norditropin SimpleXx)</td>
<td>SOMATROPIN, somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge (Norditropin SimpleXx)</td>
<td></td>
</tr>
<tr>
<td>10448X SOMATROPIN</td>
<td>10448X SOMATROPIN</td>
<td></td>
</tr>
<tr>
<td>SOMATROPIN, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge (Norditropin SimpleXx)</td>
<td>SOMATROPIN, somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge (Norditropin SimpleXx)</td>
<td></td>
</tr>
<tr>
<td>10451C SOMATROPIN</td>
<td>10451C SOMATROPIN</td>
<td></td>
</tr>
<tr>
<td>SOMATROPIN, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge (Norditropin FlexPro)</td>
<td>SOMATROPIN, somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge (Norditropin FlexPro)</td>
<td></td>
</tr>
<tr>
<td>10478L SOMATROPIN</td>
<td>10478L SOMATROPIN</td>
<td></td>
</tr>
<tr>
<td>SOMATROPIN, somatropin 30 units (10 mg/2 mL) injection, 2 mL cartridge (NutropinAq)</td>
<td>SOMATROPIN, somatropin 10 mg/2 mL injection, 2 mL cartridge (NutropinAq)</td>
<td></td>
</tr>
<tr>
<td>10496K SOMATROPIN</td>
<td>10496K SOMATROPIN</td>
<td></td>
</tr>
<tr>
<td>SOMATROPIN, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge (Norditropin FlexPro)</td>
<td>SOMATROPIN, somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge (Norditropin FlexPro)</td>
<td></td>
</tr>
<tr>
<td>10506Y SOMATROPIN</td>
<td>10506Y SOMATROPIN</td>
<td></td>
</tr>
<tr>
<td>SOMATROPIN, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge (Omnitrope Surepal 10)</td>
<td>SOMATROPIN, somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge (Omnitrope Surepal 10)</td>
<td></td>
</tr>
<tr>
<td>10514J SOMATROPIN</td>
<td>10514J SOMATROPIN</td>
<td></td>
</tr>
<tr>
<td>SOMATROPIN, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge (Omnitrope Surepal 10)</td>
<td>SOMATROPIN, somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge (Omnitrope Surepal 10)</td>
<td></td>
</tr>
<tr>
<td>10519P SOMATROPIN</td>
<td>10519P SOMATROPIN</td>
<td></td>
</tr>
<tr>
<td>SOMATROPIN, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge (Omnitrope Surepal 10)</td>
<td>SOMATROPIN, somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge (Omnitrope Surepal 10)</td>
<td></td>
</tr>
<tr>
<td>From 10518N SOMATROPIN</td>
<td>From 10519P SOMATROPIN</td>
<td></td>
</tr>
<tr>
<td>SOMATROPIN, somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge (Omnitrope Surepal 5)</td>
<td>SOMATROPIN, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge (Omnitrope Surepal 10)</td>
<td></td>
</tr>
<tr>
<td>Source</td>
<td>Destination</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
<td>-------------</td>
</tr>
<tr>
<td>5819G</td>
<td>SOMATROPIN, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge</td>
<td>(Norditropin FlexPro)</td>
</tr>
<tr>
<td>To</td>
<td>5819G</td>
<td>SOMATROPIN, somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>From</td>
<td>6296J</td>
<td>SOMATROPIN, somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>To</td>
<td>6296J</td>
<td>SOMATROPIN, somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>From</td>
<td>9604L</td>
<td>SOMATROPIN, somatropin 30 units (10 mg/2 mL) injection, 2 mL cartridge</td>
</tr>
<tr>
<td>To</td>
<td>9604L</td>
<td>SOMATROPIN, somatropin 10 mg/2 mL injection, 2 mL cartridge</td>
</tr>
<tr>
<td>From</td>
<td>10483R</td>
<td>SOMATROPIN, somatropin 36 units (12 mg/1.5 mL) injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>To</td>
<td>10483R</td>
<td>SOMATROPIN, somatropin 12 mg/1.5 mL injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>From</td>
<td>10495J</td>
<td>SOMATROPIN, somatropin 36 units (12 mg/1.5 mL) injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>To</td>
<td>10495J</td>
<td>SOMATROPIN, somatropin 12 mg/1.5 mL injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>From</td>
<td>5824M</td>
<td>SOMATROPIN, somatropin 36 units (12 mg/1.5 mL) injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>To</td>
<td>5824M</td>
<td>SOMATROPIN, somatropin 12 mg/1.5 mL injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>From</td>
<td>10446T</td>
<td>SOMATROPIN, somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>To</td>
<td>10446T</td>
<td>SOMATROPIN, somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>From</td>
<td>10449Y</td>
<td>SOMATROPIN, somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>To</td>
<td>10449Y</td>
<td>SOMATROPIN, somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>From</td>
<td>10468Y</td>
<td>SOMATROPIN, somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>To</td>
<td>10468Y</td>
<td>SOMATROPIN, somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>From</td>
<td>10470C</td>
<td>SOMATROPIN, somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>To</td>
<td>10470C</td>
<td>SOMATROPIN, somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>From</td>
<td>10485W</td>
<td>SOMATROPIN, somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>To</td>
<td>10485W</td>
<td>SOMATROPIN, somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>From</td>
<td>10489C</td>
<td>SOMATROPIN, somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>To</td>
<td>10489C</td>
<td>SOMATROPIN, somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>From</td>
<td>10490D</td>
<td>SOMATROPIN, somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>To</td>
<td>10490D</td>
<td>SOMATROPIN, somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>From</td>
<td>5820H</td>
<td>SOMATROPIN, somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>To</td>
<td>5820H</td>
<td>SOMATROPIN, somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>From</td>
<td>6297K</td>
<td>SOMATROPIN, somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>To</td>
<td>6297K</td>
<td>SOMATROPIN, somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge</td>
</tr>
<tr>
<td>From</td>
<td>10442N</td>
<td>SOMATROPIN, somatropin 60 units (20 mg/2.5 mL) injection, 2.5 mL cartridge</td>
</tr>
</tbody>
</table>
To
10442N  SOMATROPIN, somatropin 20 mg/2.5 mL injection, 2.5 mL cartridge (Saizen)

From
10497L SOMATROPIN, somatropin 60 units (20 mg/2.5 mL) injection, 2.5 mL cartridge (Saizen)
To
10497L SOMATROPIN, somatropin 20 mg/2.5 mL injection, 2.5 mL cartridge (Saizen)

From
3388H SOMATROPIN, somatropin 60 units (20 mg/2.5 mL) injection, 2.5 mL cartridge (Saizen)
To
3388H SOMATROPIN, somatropin 20 mg/2.5 mL injection, 2.5 mL cartridge (Saizen)

Repatriation Pharmaceutical Benefits
Alterations
Alteration – Item Description
From
4462W SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM, sorbitol 3.125 g/5 mL + sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 4 x 5 mL (Micolette)
To
4462W CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL, sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 4 x 5 mL (Micolette)

From
4497Q ZINC OXIDE + MAIZE STARCH + CHLORPHENESIN + PURIFIED TALC, zinc oxide 25% + maize starch 55.85% + chlorphenesin 1% + purified talc 18.07% dusting powder, 100 g (Z.S.C.)
To
4497Q ZINC OXIDE + MAIZE STARCH + PURIFIED TALC + CHLORPHENESIN, zinc oxide 25% + maize starch 55.85% + purified talc 18.07% + chlorphenesin 1% dusting powder, 100 g (Z.S.C.)

Alteration – Manufacturer Code
4199B Waxsol – DOCUSATE, docusate sodium 0.5% ear drops, 10 mL
From HM  To GO

Advance Notices
1 May 2018
Deletion – Brand
2254P Actonel EC Combi D. UA – RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL, RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1

1 June 2018
Deletion – Brand
2273P APO-Alendronate Plus D3 and Calcium, TX – ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE, alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack
General Pharmaceutical Benefits

- AFLIBERCEPT

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

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

**Note** Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Authority required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic macular oedema (DMO)</td>
</tr>
<tr>
<td>Treatment Phase: Initial treatment</td>
</tr>
</tbody>
</table>

**Clinical criteria:**
- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
- Must be treated by an ophthalmologist or in consultation with an ophthalmologist. Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:
- a) a completed authority prescription form;
- b) a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** Any queries concerning the arrangements to prescribe may be directed to 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** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

<table>
<thead>
<tr>
<th>Authority required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic macular oedema (DMO)</td>
</tr>
<tr>
<td>Treatment Phase: Continuing treatment</td>
</tr>
</tbody>
</table>

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
### AFLIBERCEPT

**Note** Special Pricing Arrangements apply.

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

**Treatment Phase:** Initial treatment

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

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

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

Applications for authority to prescribe should be forwarded to:

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

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**Note** Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

**Authority required**

Branch retinal vein occlusion with macular oedema

**Treatment Phase:** Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to branch retinal vein occlusion (BRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;
b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note**
The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
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**

Branch retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**Note**

Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**

No 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**

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and

c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note**
The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
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**

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously been issued with an authority prescription for this drug for the same eye, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:
- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

afibercept 4 mg/0.1 mL injection, 0.1 mL vial

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVS $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2168D</td>
<td>1</td>
<td>2</td>
<td>...</td>
<td>1096.82</td>
<td>39.50</td>
<td>Eylea [BN]</td>
</tr>
</tbody>
</table>

BUDESONIDE + FORMOTEROL (EFORMOTEROL)

Note Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

Restricted benefit
Asthma

Clinical criteria:
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

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

budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVS $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11273H</td>
<td>‡1</td>
<td>5</td>
<td>...</td>
<td>44.40</td>
<td>39.50</td>
<td>* DuoResp Spiromax [TB]</td>
</tr>
</tbody>
</table>

BUDESONIDE + FORMOTEROL (EFORMOTEROL)

Note Pharmaceutical benefits that have the brand DuoResp Spiromax 200/6 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

Restricted benefit
Asthma

Clinical criteria:
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

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

budesonide 200 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVS $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8625Y</td>
<td>‡1</td>
<td>5</td>
<td>...</td>
<td>44.40</td>
<td>39.50</td>
<td>* Symbicort Turbuhaler 200/6 [AP]</td>
</tr>
</tbody>
</table>

BUDESONIDE + FORMOTEROL (EFORMOTEROL)

Note Pharmaceutical benefits that have the brand DuoResp Spiromax 400/12 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 400/12 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

Restricted benefit
Asthma

Clinical criteria:
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR
- Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR
Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

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

**Note** DuoResp Spiromax 400/12 is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

**Restricted benefit**

**Chronic obstructive pulmonary disease (COPD)**

**Clinical criteria:**
- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

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

**Note** Patient must not be on a concomitant single agent long-acting beta-2 agonist.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

---

### Budesonide 400 microgram/actuation + Formoterol (Eformoterol) Fumarate Dihydrate 12 microgram/actuation powder for inhalation, 120 actuations

<table>
<thead>
<tr>
<th>Max. Qty Packs</th>
<th>No. of RptS</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11301T</td>
<td>5</td>
<td>..</td>
<td>63.67</td>
<td>39.50</td>
<td>‡1 DuoResp Spiromax [TB]</td>
</tr>
</tbody>
</table>

---

### BUDESONIDE + FORMOTEROL (EFORMOTEROL)

**Note** Pharmaceutical benefits that have the brand DuoResp Spiromax 400/12 powder for inhalation, 120 actuations and pharmaceutical benefits that have the brand Symbicort Turbuhaler 400/12 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

**Restricted benefit**

**Asthma**

**Clinical criteria:**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

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

**Note** Symbicort 400/12 is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

**Restrict benefit**

**Chronic obstructive pulmonary disease (COPD)**

**Clinical criteria:**
- Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
- Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- The treatment must be for symptomatic treatment.

**Note** Patient must not be on a concomitant single agent long-acting beta-2 agonist.

**Note** This product is not indicated for the initiation of bronchodilator therapy in COPD.

---

### Certolizumab Pegol

**Note** Authority approval for sufficient therapy to complete a maximum of 18-20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18-20 weeks of treatment should be forwarded to:

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

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** 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 therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen, AND
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

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

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>Cimzia [UC]</td>
</tr>
</tbody>
</table>

### CERTOLIZUMAB PEGOL

**Note**

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

**A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.**

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

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

(1) **How to prescribe PBS-subsidised bDMARD therapy** (a) **Initial treatment.** Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) **Continuing treatment.** Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) **Swapping therapy.** Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) **Baseline measurements to determine response.** The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

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

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

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

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

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

- Patient must have active, or a documented history of active, ankylosing spondylitis, AND
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 to 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 to 20 weeks treatment, AND
- The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

Population criteria:

- Patient must be an adult.

Treatment criteria:

- Must be treated by a rheumatologist.

### CERTOLIZUMAB PEGOL

**Note**: TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

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

---

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

<table>
<thead>
<tr>
<th>Max. Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>1014.37</td>
<td>39.50</td>
<td>Cimzia [UC]</td>
</tr>
</tbody>
</table>

---

Schedule of Pharmaceutical Benefits – April 2018
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received (initial or continuing) PBS-subsidised therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, 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 bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that 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 prescription may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD 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 bDMARD.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

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

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients 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 bDMARD 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 bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

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

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

**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 this drug, **AND**
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.
- 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) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

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

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

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

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Continuing Treatment – balance of supply

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

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug 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
certolizumab pegol 200 mg/mL injection, 2 x 1 mL injection devices

11325C

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td></td>
<td>1014.37</td>
<td>39.50</td>
<td>Cimzia [UC]</td>
</tr>
</tbody>
</table>

**CERTOLIZUMAB PEGOL**

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: - a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, - a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and - once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

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

A patient must be assessed for response to any course of initial PBS-subsidised bDMARD treatment after 1 August 2010.

1. **(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.**
   - **(a) Initial treatment.** Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
   - **Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.**
   - Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, infliximab, 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 bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that 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 bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted bDMARD 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 bDMARD.

(2) Swapping therapy

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non- bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

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

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept: Patients 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 bDMARD 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 bDMARD therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be 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 Any queries concerning the arrangements to prescribe may be directed 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)

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 severe active rheumatoid arthritis, AND
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have severe active rheumatoid arthritis, AND
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
General Pharmaceutical Benefits

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly; AND
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction..

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

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

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

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

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

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

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

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

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

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

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

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

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

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

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

**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 18 to 20 weeks of treatment, depending on the dosage regimen, 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) a completed authority prescription form and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

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

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

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

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

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

**AND** either of the following:

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

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

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

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

**Certolizumab Pegol 200 mg/mL injection, 2 x 1 mL injection devices**

<table>
<thead>
<tr>
<th>11322X</th>
<th>Max Qty</th>
<th>Packs</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>..</td>
<td>..</td>
<td>*3005.89</td>
<td>39.50</td>
<td>Cimzia [UC]</td>
<td></td>
</tr>
</tbody>
</table>

**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 agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adults with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

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

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible.
to commence another Cycle [further details are under (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last 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 agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, 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 patients be reviewed in the month prior to completing their course of initial treatment to ensure an uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to a treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

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

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled treatment with methotrexate and sulphasalazine 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 18 to 20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note No 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) 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.

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

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11326D</td>
<td></td>
<td>1014.37</td>
<td>39.50</td>
<td></td>
<td></td>
<td>Cimzia [UC]</td>
</tr>
</tbody>
</table>

**CERTOLIZUMAB PEGOL**

**Note** TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis.

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

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

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

(1) How to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID.
therapy and exercise program requirements. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment. To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

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

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

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

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

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

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

Authority required
Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have a documented history of active ankylosing spondylitis, AND
- Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND
- Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:
- Patient must be an adult.

Treatment criteria:
- Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

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

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

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

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

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
Treatment Phase: Continuing treatment – balance of supply

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

Population criteria:
- Patient must be an adult.

Treatment criteria:
- Must be treated by a rheumatologist.

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

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

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>1014.37</td>
<td>39.50</td>
<td>Cimzia [UC]</td>
</tr>
</tbody>
</table>

CERTOLIZUMAB PEGOL

Note
TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab for adult patients with active ankylosing spondylitis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and secukinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 6 bDMARDs at any 1 time.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

1. (a) When to prescribe PBS-subsidised bDMARD therapy (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or (iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 1 for recommencement after 5 years or more and Initial 2 for recommencement after a break of less than 5 years).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

2. (a) Swapping therapy. Once initial treatment with the PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

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

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

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

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy. A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

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

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

<table>
<thead>
<tr>
<th>Authority required</th>
<th>Active ankylosing spondylitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Phase:</td>
<td>Initial 1 (new patients)</td>
</tr>
<tr>
<td>Clinical criteria:</td>
<td>• The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, ( \text{AND} )</td>
</tr>
<tr>
<td></td>
<td>• Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or secukinumab in this treatment cycle, ( \text{AND} )</td>
</tr>
<tr>
<td></td>
<td>• Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, ( \text{AND} )</td>
</tr>
<tr>
<td></td>
<td>• 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.</td>
</tr>
<tr>
<td>Population criteria:</td>
<td>• Patient must be an adult.</td>
</tr>
<tr>
<td>Treatment criteria:</td>
<td>• Must be treated by a rheumatologist.</td>
</tr>
<tr>
<td></td>
<td>The application must include details of the NSAIDs trialled, their doses and duration of treatment.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:</td>
</tr>
<tr>
<td></td>
<td>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; ( \text{AND} )</td>
</tr>
<tr>
<td></td>
<td>(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.</td>
</tr>
<tr>
<td></td>
<td>The authority application must be made in writing and must include:</td>
</tr>
<tr>
<td></td>
<td>(a) a completed authority prescription form; and</td>
</tr>
<tr>
<td></td>
<td>(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:</td>
</tr>
<tr>
<td></td>
<td>(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and</td>
</tr>
<tr>
<td></td>
<td>(ii) a completed BASDAI Assessment Form; and</td>
</tr>
<tr>
<td></td>
<td>(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and</td>
</tr>
<tr>
<td></td>
<td>(iv) a signed patient acknowledgment.</td>
</tr>
</tbody>
</table>
| | The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.
A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

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

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

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

---

**Authority required**

**Ankylosing spondylitis**

Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis, AND
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, AND
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e., for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

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

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

(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

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

Note: Any queries concerning the arrangements to prescribe may be directed 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**

**Note:** TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

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

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle (further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-
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 agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 2).

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 1).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, 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 patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

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

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received prior PBS-subsidised 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.

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
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 agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

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

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle) where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restrictions for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle (further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below).

The duration of the break in therapy will be measured from the date the last 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 agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle (Initial 1). Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred are eligible to commence a new Cycle (Initial 2).

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 1 or Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, 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 patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

---

HOBART TAS 7001

General Pharmaceutical Benefits

---
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Determination of whether a response to treatment has been demonstrated will be based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

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

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have re-trialled 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 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.

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

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

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

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

An adequate response to treatment is defined as:

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

either of the following:

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

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

**Note** Any queries concerning the arrangements to prescribe may be directed 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
certolizumab pegol 200 mg/mL injection, 2 x 1 mL injection devices

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>..</td>
<td>..</td>
<td>*3005.89</td>
<td>39.50</td>
<td>Cimzia [UC]</td>
</tr>
</tbody>
</table>

### DAPAGLIFLOZIN

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

**Note** PBS-subsidised dual oral therapy does not include combination use of:
- a gliptin with an SGLT2 inhibitor;
- 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 clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- Had red cell transfusion within the previous 3 months.

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

### DAPAGLIFLOZIN

**Note** Continuing Therapy Only:

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

### Authority required (STREAMLINED)

**7506**

Diabetes mellitus type 2

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

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

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

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

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.
Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), or a glucagon-like peptide-1.

**Authority required (STREAMLINED)**

**4991**
Diabetes mellitus type 2

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

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

**Authority required (STREAMLINED)**

**5629**
Diabetes mellitus type 2

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

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)**

**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), or a glucagon-like peptide-1 analogue.

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

**DAPAGLIFLOZIN + METFORMIN**

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

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

**DAPAGLIFLOZIN + METFORMIN**

**Note** Continuing Therapy Only:

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

**Authority required (STREAMLINED)**

5631

Diabetes mellitus type 2

**Clinical criteria:**

- Patient must have, or have had, 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) or a glucagon-like peptide-1.

### Authority required (STREAMLINED)

#### 5739
Diabetes mellitus type 2

**Treatment Phase:** Continuing treatment

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

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

### Authority required (STREAMLINED)

#### 5798
Diabetes mellitus type 2

**Clinical criteria:**
- The treatment must be in combination with a sulfonylurea, **AND**

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

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

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

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

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

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

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.

### Authority required dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

### Authority required (STREAMLINED)

#### 5657
Diabetes mellitus type 2

**Clinical criteria:**
- The treatment must be in combination with insulin, **AND**

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

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

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

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

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

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

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

## 7492 Diabetes mellitus type 2

### Treatment Phase: Continuing treatment

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

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

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

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>59.02</td>
<td>39.50</td>
<td>Xigduo XR 10/500 [AP]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>61.18</td>
<td>39.50</td>
<td>Xigduo XR 5/1000 [AP]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>59.78</td>
<td>39.50</td>
<td>Xigduo XR 10/1000 [AP]</td>
</tr>
</tbody>
</table>

## DEXAMETHASONE

### Authority required

#### Non-infectious posterior segment uveitis

**Treatment criteria:**
- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**Clinical criteria:**
- Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 6/12 or worse in the eye proposed for treatment, secondary to vitreous haze or macular oedema, **AND**
- Patient must have unilateral, asymmetric or bilateral flare-up where systemic treatment or further intensification of systemic treatment is not clinically indicated.

### dexamethasone 700 microgram implant, 1

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>1354.79</td>
<td>39.50</td>
<td>Ozurdex [AG]</td>
</tr>
</tbody>
</table>

## DEXAMETHASONE

### Authority required

#### Diabetic macular oedema (DMO)

**Treatment Phase: Initial treatment**

**Treatment criteria:**
- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**Clinical criteria:**
- Patient must have visual impairment due to diabetic macular oedema, **AND**
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, **AND**
- The condition must be diagnosed by optical coherence tomography; **OR**
- The condition must be diagnosed by fluorescein angiography, **AND**
- Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors; **OR**
- Patient must be unsuitable for treatment with VEGF inhibitors; **OR**
- Patient must have failed prior treatment with VEGF inhibitors, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**
- Patient must have had a cataract removed in the treated eye; **OR**
- Patient must be scheduled for cataract surgery in the treated eye.

**Authority approval for initial treatment of each eye must be sought.**
The first authority application for each eye must be made in writing or by telephone. A written application must include:

- a completed authority prescription form;
- a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note**
Any queries concerning the arrangements to prescribe may be directed to 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**
The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Authority required**
Diabetic macular oedema (DMO)
Treatment Phase: Continuing treatment

**Treatment criteria:**
- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for the same eye, AND
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**
- Patient must have had a cataract removed in the treated eye; OR
- Patient must be scheduled for cataract surgery in the treated eye.

**Note**
Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

dexamethasone 700 microgram implant, 1

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1354.79</td>
<td>39.50</td>
<td>0</td>
<td>Ozurdex [AG]</td>
</tr>
</tbody>
</table>

**EMPAGLIFLOZIN**

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

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

**Authority required (STREAMLINED)**
7528
Diabetes mellitus type 2
Treatment Phase: Initial treatment

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

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

The HbA1c must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a glitin is initiated.

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

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a glitin, must be documented in the patient's medical records.
empagliflozin 10 mg tablet, 30

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>61.64</td>
<td>39.50</td>
<td></td>
<td>Jardiance [BY]</td>
</tr>
</tbody>
</table>

empagliflozin 25 mg tablet, 30

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>61.64</td>
<td>39.50</td>
<td></td>
<td>Jardiance [BY]</td>
</tr>
</tbody>
</table>

EMPAGLIFLOZIN

Note

Continuing Therapy Only:

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

Authority required (STREAMLINED)

7506

Diabetes mellitus type 2

Clinical criteria:

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

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

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

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

(a) 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 treatment with a gliptin and an SGLT2 inhibitor, must be documented in the patient's medical records.

Note

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

Authority required (STREAMLINED)

4991

Diabetes mellitus type 2

Clinical criteria:

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

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 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.

Authority required (STREAMLINED)

5629

Diabetes mellitus type 2

Clinical criteria:

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

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

**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)

**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), 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.

### Emagliflozin

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jardiance [BY]</td>
<td>61.64</td>
<td>39.50</td>
<td></td>
</tr>
</tbody>
</table>

### Empagliflozin

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jardiance [BY]</td>
<td>61.64</td>
<td>39.50</td>
<td></td>
</tr>
</tbody>
</table>

**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.

### EMPAGLIFLOZIN + LINAGLIPTIN

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

### Authority required (STREAMLINED)

**7524**
Diabetes mellitus type 2
Treatment Phase: Initial treatment

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

The date and level of the qualifying HbA1c measurement must be documented in the patient's medical records at the time 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.

**Empagliflozin 10 mg + Linagliptin 5 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max. Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11269D</td>
<td></td>
<td>5</td>
<td></td>
<td>84.31</td>
<td>39.50</td>
<td>Glyxambi [BY]</td>
</tr>
</tbody>
</table>

**Empagliflozin 25 mg + Linagliptin 5 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max. Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11303X</td>
<td></td>
<td>5</td>
<td></td>
<td>84.31</td>
<td>39.50</td>
<td>Glyxambi [BY]</td>
</tr>
</tbody>
</table>

### Empagliflozin + Linagliptin

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

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

**Authority required (STREAMLINED) 7556**
Diabetes mellitus type 2
Treatment Phase: Continuing treatment

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

**Empagliflozin 10 mg + Linagliptin 5 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max. Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11310G</td>
<td></td>
<td>5</td>
<td></td>
<td>84.31</td>
<td>39.50</td>
<td>Glyxambi [BY]</td>
</tr>
</tbody>
</table>

**Empagliflozin 25 mg + Linagliptin 5 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max. Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11298P</td>
<td></td>
<td>5</td>
<td></td>
<td>84.31</td>
<td>39.50</td>
<td>Glyxambi [BY]</td>
</tr>
</tbody>
</table>

### Empagliflozin + Metformin

**Authority required (STREAMLINED) 5953**
Diabetes mellitus type 2

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

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

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

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

**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 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.

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

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

Empagliflozin 12.5 mg + Metformin Hydrochloride

Empagliflozin 12.5 mg + Metformin Hydrochloride 1 g Tablet, 60

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>64.76</td>
<td>39.50</td>
<td>Jardiamet 12.5 mg/1000 mg [BY]</td>
</tr>
</tbody>
</table>

Empagliflozin 12.5 mg + Metformin Hydrochloride 500 mg Tablet, 60

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>63.25</td>
<td>39.50</td>
<td>Jardiamet 12.5 mg/500 mg [BY]</td>
</tr>
</tbody>
</table>

Empagliflozin 5 mg + Metformin Hydrochloride 1 g Tablet, 60

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>64.76</td>
<td>39.50</td>
<td>Jardiamet 5 mg/1000 mg [BY]</td>
</tr>
</tbody>
</table>

Empagliflozin 5 mg + Metformin Hydrochloride 500 mg Tablet, 60

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>63.25</td>
<td>39.50</td>
<td>Jardiamet 5 mg/500 mg [BY]</td>
</tr>
</tbody>
</table>

Empagliflozin + Metformin

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

Authority Required (STREAMLINED)

5966
Diabetes mellitus type 2
Treatment Phase: Continuing treatment

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

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

Authority Required (STREAMLINED)

5798
Diabetes mellitus type 2

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

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

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

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

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

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

### Authority required (STREAMLINED)

#### 5657
Diabetes mellitus type 2

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

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

#### 7492
Diabetes mellitus type 2

**Treatment Phase:** Continuing treatment

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

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

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

### empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60

<table>
<thead>
<tr>
<th>10677Y</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>.</td>
<td>64.76</td>
<td>39.50</td>
<td></td>
<td>Jardiamet 12.5 mg/1000 mg [BY]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>10633P</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>.</td>
<td>63.25</td>
<td>39.50</td>
<td></td>
<td>Jardiamet 12.5 mg/500 mg [BY]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>10627H</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>.</td>
<td>64.76</td>
<td>39.50</td>
<td></td>
<td>Jardiamet 5 mg/1000 mg [BY]</td>
</tr>
</tbody>
</table>
empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60

<table>
<thead>
<tr>
<th>10626G</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>63.25</td>
<td>39.50</td>
<td></td>
<td>Jardiamet 5 mg/500 mg [BY]</td>
</tr>
</tbody>
</table>

**GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS**

*Restricted benefit*
Phenylketonuria

glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g of protein equivalent powder for oral liquid, 60 x 16 g sachets

<table>
<thead>
<tr>
<th>11287C</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>1072.79</em></td>
<td>39.50</td>
<td></td>
<td>PKU Build 10 [QH]</td>
</tr>
</tbody>
</table>

glycomacropeptide and essential amino acids with vitamins and minerals containing 20 g of protein equivalent powder for oral liquid, 30 x 32 g sachets

<table>
<thead>
<tr>
<th>11279P</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>2068.43</em></td>
<td>39.50</td>
<td></td>
<td>PKU Build 20 [QH]</td>
</tr>
</tbody>
</table>

**GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS**

*Restricted benefit*
Tyrosinaemia

glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g of protein equivalent bar, 14 x 81 g

<table>
<thead>
<tr>
<th>11290F</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>2904.67</em></td>
<td>39.50</td>
<td></td>
<td>Tylactin Complete [QH]</td>
</tr>
</tbody>
</table>

**INSULIN GLARGINE**

insulin glargine 300 units/mL injection, 3 x 1.5 mL injection devices

<table>
<thead>
<tr>
<th>11308E</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>366.10</em></td>
<td>39.50</td>
<td></td>
<td>Toujeo Solostar [SW]</td>
</tr>
</tbody>
</table>

insulin glargine 300 units/mL injection, 5 x 1.5 mL injection devices

<table>
<thead>
<tr>
<th>11302W</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>607.00</em></td>
<td>39.50</td>
<td></td>
<td>Toujeo Solostar [SW]</td>
</tr>
</tbody>
</table>

**LINAGLIPTIN**

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

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

**Authority required (STREAMLINED)**

7541
Diabetes mellitus type 2
Treatment Phase: Initial treatment

**Clinical criteria:**
- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with dual oral combination therapy with metformin and an SGLT2 inhibitor; **OR**
- Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a glitpin.

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 glitpin 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 glitpin 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 glitpin, must be documented in the patient's medical records.
LINAGLIPTIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing 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, an 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 glitin, 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, an 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 glitin, 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.

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

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

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

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

### Authority required (STREAMLINED) 7505
Diabetes mellitus type 2

**Treatment Phase: Continuing treatment**

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

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

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

### LINagliptin + Metformin

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

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

### Authority required (STREAMLINED) 7507
Diabetes mellitus type 2

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, AND
- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and an SGLT2 inhibitor for this condition; OR
- Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

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

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

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

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

---

**linagliptin 5 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3387G</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>59.61</td>
<td>Trajenta [BY]</td>
</tr>
</tbody>
</table>
LINAGLIPTIN + METFORMIN

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)

Diabetes mellitus type 2

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

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

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

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

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

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

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

Authority required (STREAMLINED)

Diabetes mellitus type 2

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

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

Authority required (STREAMLINED)

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**

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

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

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

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

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

**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**

**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.

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10044P</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of Rpts</td>
<td>5</td>
<td>62.74</td>
<td>39.50</td>
<td></td>
<td>Trajentamet [BY]</td>
</tr>
</tbody>
</table>

### linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10045Q</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of Rpts</td>
<td>5</td>
<td>62.30</td>
<td>39.50</td>
<td></td>
<td>Trajentamet [BY]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10038H</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of Rpts</td>
<td>5</td>
<td>61.23</td>
<td>39.50</td>
<td></td>
<td>Trajentamet [BY]</td>
</tr>
</tbody>
</table>

#### METHOTREXATE

**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.

---

General Pharmaceutical Benefits 59
Severe psoriasis

Clinical criteria:
- The condition must not have adequately responded to topical treatment, AND
- Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

**methotrexate 15 mg/0.3 mL injection, 0.3 mL syringe**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11268C</td>
<td>4</td>
<td>5</td>
<td>…</td>
<td>*88.51</td>
<td>39.50 Trexject [LM]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11275K</td>
<td>4</td>
<td>5</td>
<td>…</td>
<td>*88.51</td>
<td>39.50 Trexject [LM]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11288D</td>
<td>4</td>
<td>5</td>
<td>…</td>
<td>*88.51</td>
<td>39.50 Trexject [LM]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11283W</td>
<td>4</td>
<td>5</td>
<td>…</td>
<td>*88.51</td>
<td>39.50 Trexject [LM]</td>
</tr>
</tbody>
</table>

**methotrexate 25 mg/0.5 mL injection, 0.5 mL syringe**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11295L</td>
<td>4</td>
<td>5</td>
<td>…</td>
<td>*88.51</td>
<td>39.50 Trexject [LM]</td>
</tr>
</tbody>
</table>

**RANIBIZUMAB**

Note No 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 Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**Authority required**

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

Clinical criteria:
- Patient must have visual impairment due to diabetic macular oedema, AND
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, AND
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, AND
- The treatment must be as monotherapy; OR
- The treatment must be in combination with laser photocoagulation, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:
- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

A written application must include:
- a completed authority prescription form;
- a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

Note The first authority application may be faxed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.
**Authority required**
Diabetic macular oedema (DMO)
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must be in combination with laser photocoagulation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**Note**
Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

---

**ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>5</td>
<td></td>
<td>1149.44</td>
<td>Lucentis [NV]</td>
</tr>
</tbody>
</table>

---

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>5</td>
<td></td>
<td>1149.44</td>
<td>Lucentis [NV]</td>
</tr>
</tbody>
</table>

---

**RANIBIZUMAB**

**Note**
Special Pricing Arrangements apply.

**Note**
Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

---

**Authority required**
Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Initial treatment

**Clinical criteria:**
- The condition must be due to age-related macular degeneration (AMD), **AND**
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made in writing or by telephone. A written application must include:

- a completed authority prescription form;
- b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
- c) a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note**
The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

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

Applications for authority to prescribe should be forwarded to:

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

---

**Authority required**
Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Continuing treatment

**Clinical criteria:**
- The condition must be due to age-related macular degeneration (AMD), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been granted an authority prescription for the same eye.

**Treatment criteria:**
- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**Note**
Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Authority required
Branch retinal vein occlusion with macular oedema
Treatment Phase: Initial treatment
Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to branch retinal vein occlusion (BRVO), AND
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, AND
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made in writing or by telephone.
A written application must include:
- a completed authority prescription form;
- a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.

A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

Note
The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

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

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

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

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

Authority required
Branch retinal vein occlusion with macular oedema
Treatment Phase: Continuing treatment
Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for the same eye, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Authority required
Central retinal vein occlusion with macular oedema
Treatment Phase: Initial treatment
Clinical criteria:

- Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), AND
- Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, AND
- The condition must be diagnosed by optical coherence tomography; OR
- The condition must be diagnosed by fluorescein angiography, AND
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Authority approval for initial treatment of each eye must be sought. The first authority application for each eye must be made in writing or by telephone.
A written application must include:
- a completed authority prescription form;
- a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form; and
- a copy of the optical coherence tomography or fluorescein angiogram report.
A telephone application must be made following submission by facsimile of a copy of a completed Retinal Vein Occlusion Initial PBS authority application Supporting information form and a copy of the optical coherence tomography or fluorescein angiogram report.

**Note** The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

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

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

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

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

**Authority required**
Central retinal vein occlusion with macular oedema
Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for this drug for the same eye, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

**Note** Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

---

**ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10138N</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>1149.44</td>
<td>39.50</td>
</tr>
</tbody>
</table>

**ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1382R</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>1149.44</td>
<td>39.50</td>
</tr>
</tbody>
</table>

---

**SAXAGLIPTIN**

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

**Note** PBS-subsidised dual oral therapy does not include combination use of:
- a gliptin with an SGLT2 inhibitor; or
- 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.
saxagliptin 2.5 mg tablet, 28
11292H
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 56.38 39.50 Onglyza [AP]

saxagliptin 5 mg tablet, 28
11311H
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 5 .. 56.38 39.50 Onglyza [AP]

SAXAGLIPTIN

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

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.

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.
Diabetes mellitus type 2
Treatment Phase: Continuing treatment

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

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

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

---

### saxagliptin 2.5 mg tablet, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td></td>
<td>56.38</td>
<td>39.50</td>
<td>Onglyza [AP]</td>
</tr>
</tbody>
</table>

### saxagliptin 5 mg tablet, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td></td>
<td>56.38</td>
<td>39.50</td>
<td>Onglyza [AP]</td>
</tr>
</tbody>
</table>

**SAXAGLIPTIN + DAPAGLIFLOZIN**

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

**Authority required (STREAMLINED)**

7524
Diabetes mellitus type 2
Treatment Phase: Initial treatment

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

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

The HbA1c must be no more than 4 months old at the time triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin is initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
- **(a)** 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.

---

### saxagliptin 5 mg + dapagliflozin 10 mg tablet, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td></td>
<td>79.43</td>
<td>39.50</td>
<td>Qtern 5/10 [AP]</td>
</tr>
</tbody>
</table>

**SAXAGLIPTIN + DAPAGLIFLOZIN**

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

**Note** Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing 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.

**SAXAGLIPTIN + METFORMIN**

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

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

---

**SAXAGLIPTIN + METFORMIN**

**Note** Continuing Therapy Only:

- Had red cell transfusion within the previous 3 months.
- A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- A clinical condition with increased red cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- An SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
- An SGLT2 inhibitor is initiated.
- A gliptin is initiated.
- Metformin and a gliptin.

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

The HbA1c must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
- A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- A clinical condition with increased red cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- An SGLT2 inhibitor was initiated.

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

---

**Authority required (STREAMLINED)**

**7507**

Diabetes mellitus type 2

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, **AND**
- Patient must have an HbA1c measurement greater than 7% despite treatment with a PBS-subsidised regimen of oral diabetic medicines which includes metformin and an SGLT2 inhibitor for this condition; **OR**
- Patient must have, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation of triple oral therapy with a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin.

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

The HbA1c must be no more than 4 months old at the time of initiation of triple oral therapy with an SGLT2 inhibitor, metformin and a gliptin.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
- A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- A clinical condition with increased red cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- An SGLT2 inhibitor was initiated.

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

---

**Authority required (STREAMLINED)**

**6333**

Diabetes mellitus type 2

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

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time of 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 was initiated.

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

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:
- A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- A clinical condition with increased red cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- An SGLT2 inhibitor was initiated.

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

---
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)**

### 6325

**Diabetes mellitus type 2**

**Treatment Phase:** Continuing

**Clinical criteria:**

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

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

**Authority required (STREAMLINED)**

### 6344

**Diabetes mellitus type 2**

**Clinical criteria:**

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

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

### 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.

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10048W</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>59.29</td>
<td>39.50</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10055F</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>57.13</td>
<td>39.50</td>
</tr>
</tbody>
</table>
SONIDEGIB

Caution Sonidegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 20 months and 6 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

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

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

Note Special Pricing Arrangements apply.

**Authority required**

Metastatic or locally advanced basal cell carcinoma

**Clinical criteria:**

- The condition must be inappropriate for surgery, **AND**
- The condition must be inappropriate for curative radiotherapy, **AND**
- Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; **OR**
- Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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

a) A completed authority prescription form; and
b) A completed Basal Cell Carcinoma Initial PBS Authority Application Form - Supporting Information Form; and
c) A histological confirmation of BCC and whether the condition is metastatic or locally advanced; and
d) A letter from a surgically qualified clinician demonstrating inappropriateness for surgery for patients with locally advanced BCC; and
e) A letter from a radiation oncologist demonstrating inappropriateness for curative radiotherapy for patients with locally advanced BCC; and
f) A signed patient acknowledgement.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

**Inappropriate for surgery is defined as:**

i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

iii/ Medical contraindication to surgery

**Inappropriate for curative radiotherapy is defined as:**

i/ Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

ii/ Limitations due to location of tumour; or

iii/ Limitations due to cumulative prior radiotherapy dose; or

iv/ Progressive disease despite prior irradiation of locally advanced BCC.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001
The authority application must be made in writing and must include:

a) A completed authority prescription form; and
b) A completed Basal Cell Carcinoma Continuing PBS Authority Application Form - Supporting Information Form; and

c) A confirmation statement from the treating doctor that the disease has not progressed; and

d) In patients with locally advanced BCC, a letter from a surgically qualified clinician demonstrating that the condition remains inappropriate for surgery; or a letter from a radiation oncologist demonstrating that the condition remains inappropriate for curative radiotherapy.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

**Inappropriate for surgery is defined as:**

i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

iii/ Medical contraindication to surgery

**Inappropriate for curative radiotherapy is defined as:**

i/ Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

ii/ Limitations due to location of tumour; or

iii/ Limitations due to cumulative prior radiotherapy dose; or

iv/ Progressive disease despite prior irradiation of locally advanced BCC

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

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

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

---

**sonidegib 200 mg capsule, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>..</td>
<td>7970.95</td>
<td>39.50</td>
<td>Odomzo [RA]</td>
</tr>
</tbody>
</table>

---

**TENOFOVIR + EMTRICITABINE**

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

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

Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg tablet, tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg tablet, and tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg tablet are equivalent for the purposes of substitution.

---

**Authority required (STREAMLINED)**

7580

Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection

**Clinical criteria:**

- The treatment must be for patients at medium to high risk of HIV infection, as defined by the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) Guidelines. **AND**

- Patient must have a negative HIV test result prior to treatment with PBS-subsidised therapy with this drug.

**Population criteria:**

- Patient must be 18 years or older.
tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>249.99</td>
<td>39.50</td>
<td>* Truvada [GI]</td>
</tr>
</tbody>
</table>

tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>249.99</td>
<td>39.50</td>
<td>* Tenofovir EMT GH [GQ]</td>
</tr>
</tbody>
</table>

tenovo disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>249.99</td>
<td>39.50</td>
<td>* Tenofovir Disoproxil</td>
</tr>
</tbody>
</table>

VERTEPORFIN

Note: A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

Note: The Department of Human Services should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.

Authority required (STREAMLINED)

7583
Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Continuing treatment

Clinical criteria:
- The condition must be predominantly classic (greater than or equal to 50%), AND
- The condition must be due to macular degeneration, AND
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- Patient must have previously been granted an authority prescription for the same eye.

Treatment criteria:
- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Verteporfin 15 mg injection, 1 vial

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>2142.00</td>
<td>39.50</td>
<td>Visudyne [NV]</td>
</tr>
</tbody>
</table>

VERTEPORFIN

Note: The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note: The Department of Human Services should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.

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

Authority required
Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Initial treatment

Clinical criteria:
- The condition must be predominantly classic (greater than or equal to 50%).

Treatment criteria:
- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

Clinical criteria:
- The treatment must be the sole PBS-subsidised therapy for this condition, AND
- The condition must be due to age-related macular degeneration (AMD), AND
- The condition must be diagnosed by fluorescein angiography, AND
- Patient must have a baseline visual acuity equal to or better than 6/60 (20/200).

The first authority application for each eye must be made in writing or by telephone. A written application must include:
- a completed authority prescription form;
- a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
- a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).
A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram.

**Note** No more than 15 treatments (1 initial and 14 continuing) per eye will be authorised.

**Authority required**
Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Initial PBS-subsidised treatment

**Clinical criteria:**
- The condition must be predominantly classic (greater than or equal to 50%), **AND**
- The condition must be due to macular degeneration, **AND**
- Patient must have been authorised by the Angiogram Review Panel to receive treatment with verteporfin in the same eye under the MBS Visudyne Therapy Program, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**
- Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

The first authority application for each eye must be made in writing or by telephone. A written application must include:
(a) a completed authority prescription form; and
(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form, which includes the date of review by the Angiogram Review Panel and the number of treatments administered in that eye under the MBS Visudyne Therapy Program; and
(c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).
A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram.

**Note** A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

---

**Verteporfin 15 mg injection, 1 vial**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>2142.00</td>
<td>39.50</td>
<td>Visudyne [NV]</td>
<td></td>
</tr>
</tbody>
</table>

**Vildagliptin**

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

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

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

**Authority required (STREAMLINED)**

**6363**
Diabetes mellitus type 2

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

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

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

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

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

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

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

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

### Authority required (STREAMLINED)

**6376**

**Diabetes mellitus type 2**

**Clinical criteria:**

- The treatment must be in combination with insulin, AND

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

- 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 anti-diabetic agents, or insulin alone where metformin is contraindicated.

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

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

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

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

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

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

### vildagliptin 50 mg tablet, 60

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>59.61</td>
<td>39.50</td>
<td>Galvus [NV]</td>
</tr>
</tbody>
</table>

**VILDAGLIPTIN + METFORMIN**

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

**Note Continuing Therapy Only:**

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

### Authority required (STREAMLINED)

**6333**

**Diabetes mellitus type 2**

**Clinical criteria:**

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

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

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

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

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

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

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

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

**Authority required (STREAMLINED)**

6357

Diabetes mellitus type 2

**Treatment Phase: Continuing**

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

**Authority required (STREAMLINED)**

6344

Diabetes mellitus type 2

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

The 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 is initiated.

**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 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 is initiated.

**Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:**
- Had red cell transfusion within the previous 3 months.
- A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and vildagliptin.

The date and level of the qualifying HbA1c measurement must be, or must have been, 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** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

---

**vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Galvumet 50/500 [NV]</td>
<td>1</td>
<td>59.81</td>
<td>39.50</td>
<td>39.50</td>
</tr>
</tbody>
</table>

---

**General Pharmaceutical Benefits**
vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60

<table>
<thead>
<tr>
<th></th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5475E</td>
<td>1</td>
<td>5</td>
<td></td>
<td>59.88</td>
<td>39.50</td>
<td>Galvumet 50/850 [NV]</td>
</tr>
</tbody>
</table>

vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60

<table>
<thead>
<tr>
<th></th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5476F</td>
<td>1</td>
<td>5</td>
<td></td>
<td>60.32</td>
<td>39.50</td>
<td>Galvumet 50/1000 [NV]</td>
</tr>
</tbody>
</table>

**VISMODEGIB**

**Caution** Vismodegib is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 24 months and 2 months period after cessation of treatment for female and male patients respectively, as according to the TGA approved Product Information.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Metastatic or locally advanced basal cell carcinoma

**Treatment Phase:** Initial treatment

**Clinical criteria:**

- The condition must be inappropriate for surgery, **AND**
- The condition must be inappropriate for curative radiotherapy, **AND**
- Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; **OR**
- Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

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

- A completed authority prescription form; and
- A completed Basal Cell Carcinoma Initial PBS Authority Application Form - Supporting Information Form; and
- A histological confirmation of BCC and whether the condition is metastatic or locally advanced; and
- A letter from a surgically qualified clinician demonstrating inappropriateness for surgery for patients with locally advanced BCC; and
- A letter from a radiation oncologist demonstrating inappropriateness for curative radiotherapy for patients with locally advanced BCC; and
- A signed patient acknowledgement.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

**Inappropriate for surgery is defined as:**

- Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or
- Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or
- Medical contraindication to surgery

**Inappropriate for curative radiotherapy is defined as:**

- Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or
- Limitations due to location of tumour; or
- Limitations due to cumulative prior radiotherapy dose; or
- Progressive disease despite prior irradiation of locally advanced BCC.

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

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

Applications for authority to prescribe should be forwarded to:

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

**Authority required**

Metastatic or locally advanced basal cell carcinoma

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
• Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition, AND
• The condition must remain inappropriate for surgery, AND
• The condition must remain inappropriate for curative radiotherapy, AND
• Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.

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

a) A completed authority prescription form; and
b) A completed Basal Cell Carcinoma Continuing PBS Authority Application Form - Supporting Information Form; and
c) A confirmation statement from the treating doctor that the disease has not progressed; and
d) In patients with locally advanced BCC, a letter from a surgically qualified clinician demonstrating that the condition remains inappropriate for surgery; or a letter from a radiation oncologist demonstrating that the condition remains inappropriate for curative radiotherapy.

The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Inappropriate for surgery is defined as:

i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or

ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or

iii/ Medical contraindication to surgery

Inappropriate for curative radiotherapy is defined as:

i/ Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or

ii/ Limitations due to location of tumour; or

iii/ Limitations due to cumulative prior radiotherapy dose; or

iv/ Progressive disease despite prior irradiation of locally advanced BCC.

Note

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

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

Applications for authority to prescribe should be forwarded to:

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

Authority required
Metastatic or locally advanced basal cell carcinoma
Treatment Phase: Initial treatment or Continuing treatment – balance of supply

Clinical criteria:

• Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR

• Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment, AND

• The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Highly Specialised Drugs Program
(Community Access)

**LANREOTIDE**

**Authority required (STREAMLINED)**

7532
Acromegaly

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- 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 who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.
- The condition must be active,
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre,
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

**Authority required (STREAMLINED)**

7509
Functional carcinoid tumour

**Clinical criteria:**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somatuline Autogel [IS]</td>
<td>4303.15</td>
<td>39.50</td>
<td></td>
</tr>
</tbody>
</table>

**lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somatuline Autogel [IS]</td>
<td>3448.15</td>
<td>39.50</td>
<td></td>
</tr>
</tbody>
</table>

**lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somatuline Autogel [IS]</td>
<td>2602.65</td>
<td>39.50</td>
<td></td>
</tr>
</tbody>
</table>